



# Reimportation: The Solution to the High Cost of Prescription Drugs?

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REIMPORTATION: THE SOLUTION TO THE HIGH COST OF PRESCRIPTION DRUGS?

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## **ABSTRACT**

This paper is about a provision in the recently enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003 allowing the reimportation of prescription drugs from Canada under specified conditions. This paper will examine the existing laws prior to the passage of the act, what the new legislation entails, and the likely effect of the legislation. This paper will also examine the underlying policy issues involved in reimportation generally, as well as the reasons why prescription drugs are priced as they are both in the U.S. and Canada. The paper will examine the safety and cost repercussions of a reimportation system, and will evaluate the benefits and risks of reimportation.

## **Introduction**

Many Americans are buying their prescription drugs from Canada. Among them is Charles Spect, 62, a retired county worker who lives near Pittsburgh, who began buying prescription drugs online from Canada in 2002 in order to save money on his heart and blood pressure medications. He takes 12 pills a day. By importing his drugs from Canada, he has lowered his costs for a three-month supply from \$600 to \$350.<sup>1</sup> Charles is one of a multitude of such people who realize significant cost savings by buying prescription drugs from Canada. “In effect, Canada has become the United States’ favorite drugstore for seniors – and its de facto Medicare drug benefit.”<sup>2</sup> However, by and large, most of the drugs coming in from Canada are

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<sup>1</sup>Gilbert M. Gaul & Mary Pat Flaherty, *Canada is a Discount Pharmacy for Americans; FDA Doing Little to Stop Cross-Border Trade in Drugs*, WASH. POST, Oct. 23, 2003, at A17.

<sup>2</sup>*Id.*

coming in illegally.<sup>3</sup>

Prescription drugs that are manufactured in the U.S. and sold abroad can only be imported into the U.S. by the original drug manufacturer. However, the original drug manufacturer has no incentive to reimport drugs into the U.S. As a result, there has been significant effort to pass meaningful legislation that would allow reimportation of prescription drugs. Legislation was recently passed that, if put into effect, could allow such reimportation. However, it is unlikely that this legislation will become effective. States and cities have also entered the debate about reimportation. Iowa, Illinois, West Virginia, Minnesota, and New Hampshire have proposed plans to save money on employee health insurance and other health programs by reimporting drugs from Canada.<sup>4</sup> Boston Mayor Thomas Menino also proposed plans to reimport drugs from Canada for city workers, beginning in June 2004.<sup>5</sup>

Proponents of reimportation argue that prescription drug prices in the U.S. are significantly higher than drug prices in Canada. An estimated one million Americans are already buying medicines from other countries, and there are few reports of ill effects.<sup>6</sup> Rather than fight the practice, the FDA should focus on ensuring the quality of imported drugs. On the other side of the debate is the FDA's argument that they cannot ensure the quality of drugs imported from foreign sources. Also, the pharmaceutical industry claims that the high prices are necessary because of the high costs of research and development. This paper will examine both the safety and the pricing claims, and will discuss the policy issues involved with reimportation.

### **The Existing Law**

Section 801(a) of the Food, Drug, and Cosmetic Act (FDCA) requires the FDA, working with Customs, to

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<sup>3</sup>*Id.*

<sup>4</sup>Christian Bourge, *Analysis: Rx Fixes Face Reality*, UNITED PRESS INT'L, Apr. 9, 2004.

<sup>5</sup>*Reimportation: Boston Mayor Announces New Pilot Program*, AMERICAN HEALTH LINE, Feb. 23, 2004.

<sup>6</sup>"*Importing Prescription Drugs: Balancing Affordability and Public Health, Foreword*," 82 CONG. DIGEST 257, Nov. 2003.

prevent the importation of any drugs that appear to be adulterated, misbranded, or unapproved.<sup>7</sup> Under section 501 of the FDCA, a drug is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance; if it has been prepared, packed, or held under insanitary conditions; if it was not manufactured in conformity with current good manufacturing practices; if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; if it contains an unsafe color additive; or it falls below the requirements of strength, quality, or purity.<sup>8</sup> A drug is misbranded if, among other things, it has a false or misleading label; if it is in package form unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; if any word, statement, or other information required to appear on the label is not prominently placed; if it lacks adequate directions for intended use; if it is an imitation of another drug; or if it fails to contain adequate warnings against dangerous use in pathological conditions or by children or against unsafe dosages or methods of administration.<sup>9</sup>

Under the approval requirements in FDCA section 505, every new drug sold in the U.S. must be approved in advance by the FDA based on proof of safety and effectiveness. No person may introduce into interstate commerce a new drug unless it is covered by an approved new drug application (NDA) or an approved abbreviated new drug application (ANDA).<sup>10</sup> Approval of an application applies only to that specific drug. When a product without an approved application is introduced into interstate commerce, it is considered an unapproved new drug and therefore violates section 505 of the FDCA. It is also considered misbranded under section 502 of the FDCA. These rules cover imports, because imports introduce drugs into interstate commerce. If a product is identical to an FDA-approved product, but itself has not yet been approved

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<sup>7</sup>FDCA § 801(a).

<sup>8</sup>FDCA § 501.

<sup>9</sup>FDCA § 502.

<sup>10</sup>FDCA §§ 301(d) & 505(a).

approved by the FDA for sale in the U.S., it may not be imported. This applies even if it is approved in the country it is exported from. Therefore, under these provisions, before a product may be imported into the United States the importer must demonstrate that the imported product is in full compliance with an approved NDA or ANDA and is not misbranded or adulterated.

The Prescription Drug Marketing Act of 1987 (PDMA) expressly banned the reimportation of pharmaceuticals manufactured in the United States and sold abroad by anyone other than the original drug manufacturer.<sup>11</sup> The purpose of the PDMA was to keep sub-potent or adulterated drugs from inadvertently ending up in retail pharmacies in the United States.<sup>12</sup> The PDMA was passed in response to a series of Congressional Oversight hearings by the House Energy and Commerce Committee’s Oversight and Investigations Subcommittee. These hearings investigated the problems resulting from insufficient oversight of reimportation from abroad. The Subcommittee found importation of counterfeit and ineffective drugs, as well as reimported drugs that were expired or stored improperly.<sup>13</sup> In one instance, over two million unapproved and potentially unsafe and ineffective Ovulen 21 birth control tablets from Panama were distributed throughout the U.S. They were falsely imported as “American goods returned.”<sup>14</sup> In another case, a counterfeit version of Celcor, a widely used antibiotic at the time, found its way into the U.S. drug distribution from a foreign source.<sup>15</sup> These high profile cases prompted the passage of PDMA.

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<sup>11</sup>FDCA § 801(d)(1).

<sup>12</sup>*Drug Importation Policy: Current Laws and Issues for Debate*, 82 CONG. DIGEST 262, 262 (Nov. 2003)(From Library of Congress, Congressional Research Service Report, *Importing Prescription Drugs – Comparison of the Drug Import Provisions in the Medicare Reform Bills, H.R. 2427, and Current Law*, Oct. 8, 2003)..

<sup>13</sup>*See, e.g.*, 99<sup>th</sup> CONG., 2<sup>nd</sup> SESS. 22, DANGEROUS MEDICINE: THE RISK TO AMERICAN CONSUMERS FROM PRESCRIPTION DRUG DIVERSION AND COUNTERFEITING (Comm. Print 99-2 1986).

<sup>14</sup>*U.S. Senate Hearing on Drug Importation, Before the Comm. on Commerce, Science, and Transportation*, 108<sup>th</sup> Cong. (Nov. 20, 2003) (statement of John M. Taylor, III, Associate Commissioner for Regulatory Affairs, Food and Drug Administration), available at <http://www.fda.gov/ola/2003/rxdrugs1120.html>.

<sup>15</sup>*Id.*

However, despite the restriction that only drug manufacturers can legally import prescription drugs into the U.S., the FDA has exercised its discretion to permit imports for personal use under specified circumstances.<sup>16</sup> The personal use guidance was first adopted in 1954, and it was modified in 1988 in response to concerns that certain AIDS treatments were not available in the United States.<sup>17</sup> The guidance allows individuals with serious conditions to get treatments that are legally available in foreign countries but are not approved in the United States.<sup>18</sup>

The personal use policy is not a law or regulation, but rather serves as guidance for FDA personnel. The importation of certain unapproved prescription drugs for personal use may be allowed if all of these factors apply:

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If the intended use is for a serious condition for which effective treatment may not be available domestically.

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If the product is not considered to represent an unreasonable risk.

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<sup>16</sup>See FDA Regulatory Procedures Manual, Chp. 9, Subchapter *Coverage of Personal Importations*.

<sup>17</sup>FDA, *Imported Drugs Raise Safety Concerns*, FDA CONSUMER MAG., Sept.– Oct. 2002, available at [http://www.fda.gov/fdac/features/2002/502\\_import.html](http://www.fda.gov/fdac/features/2002/502_import.html).

<sup>18</sup>*Id.*

If the individual seeking to import the drug affirms in writing that it is for the patient's own use and provides the name and address of the U.S. licensed doctor responsible for his or her treatment with the drug or provides evidence that the drug is for continuation of a treatment begun in a foreign country.

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If the product is for personal use and is a three-month supply or less and is not for resale.

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If there is no known commercialization or promotion to U.S. residents by those involved in distribution of the product.<sup>19</sup>

Saving money on prescription drugs is not one of the factors considered in the personal use policy. The policy simply describes the FDA's enforcement priorities, and does not change the law. The FDA maintains the right to prosecute those importing illegal drugs into the U.S. As a practical matter, the FDA focuses its resources on imported drugs it perceives to pose the greatest health risks.

For example, the FDA recently took action against Rx Depot. Rx Depot was incorporated under the laws of the State of Nevada, and does business throughout the United States. Rx Depot "assists individuals in procuring prescription medications from pharmacies in Canada."<sup>20</sup> An Oklahoma state court recently ordered Rx Depot's stores in Oklahoma to close after finding that they were storefronts for Canadian pharmacies and, as such, were operating as unlicensed pharmacies.<sup>21</sup> After making undercover purchases, the FDA sent a warning letter to Rx Depot on March 21, 2003. The letter informed Rx Depot that the FDA believed them to be violating FDCA section 801 because they caused prescription drugs manufactured in the United States to be reimported by persons other than the manufacturer of the drug. Further, the letter

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<sup>20</sup>United States v. Rx Depot, Inc., 290 F. Supp. 2d 1238, 1240 (N.D. Okla. 2003).

<sup>21</sup>*Id.* at 1241.



stated that the defendants violated FDCA section 505 by causing unapproved new drugs to be imported into the United States. Rx Depot did not indicate any intention of halting their practices.

Therefore, the FDA sought a preliminary injunction to stop Rx Depot from further FDCA violations. The district court granted the injunction. Rx Depot argued selective enforcement by the FDA of their personal importation policy.<sup>22</sup> The court found this argument unavailing, because the FDA's personal importation policy outlines specific circumstances in which the agency generally will decline to prosecute the illegal importation of small quantities of prescription drugs by individuals.<sup>23</sup> By its express terms, this policy of enforcement discretion does not apply to commercial operations such as Rx Depot.

In addition, the FDA has issued statements that the personal importation policy presents a threat to public health. In a hearing before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce in June 2001, William Hubbard, the Senior Associate Commissioner for Policy, Planning and Legislation of the FDA, stated that "importing prescription drugs for personal use is a potentially dangerous practice."<sup>24</sup> He also stated that the need for the personal importation policy is far less now than it was when the current version of the policy was developed in 1988.<sup>25</sup>

In a 2002 hearing before the Subcommittee on Health of the House Committee on Energy and Commerce, Hubbard stated that the personal importation policy, as written, is difficult to implement with respect to mail shipments of drugs.<sup>26</sup> This is due in part to the difficulty faced by Customs or FDA inspectors in identi-

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<sup>22</sup>*Id.* at 1248.

<sup>23</sup>*Id.*

<sup>24</sup>*Continuing Concerns Over Imported Pharmaceuticals, Hearing Before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, 107<sup>th</sup> Cong. (June 7, 2001)(statement of William Hubbard), available at <http://www.fda.gov/ola/2001/drugimport0607.html>.*

<sup>25</sup>*Id.*

<sup>26</sup>*Examining Prescription Drug Reimportation: a Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs, Hearing Before the Subcommittee on Health of the House Committee on Energy and Commerce, 107<sup>th</sup> Cong. (Jul. 25, 2002)(statement of William Hubbard), available at <http://energycommerce.house.gov/107/hearings/07252002Hearing677/Hubbard1147.htm>.*

fying a medicine simply by its appearance or its labeling, which may falsely identify a product.<sup>27</sup> Practically, FDA inspectors cannot visually examine drugs contained in mailed parcels and accurately determine their identity or the degree of risk posed to the individual who will receive these drugs.<sup>28</sup> Also, because of Internet sites selling prescription drugs from all around the world, the volume of parcels containing prescription drugs has increased dramatically, beyond the ability of Customs and FDA to efficiently process.<sup>29</sup> For example, two million packages of pharmaceuticals arrive annually by international mail from Thailand, India, South Africa, Canada, and other points.<sup>30</sup> At the Washington Dulles International Airport mail site, between ten and fifteen tractor-trailer loads of international parcels arrive daily.<sup>31</sup> Enforcement agents who peer through x-ray scanners and examine labels looking for pills and vials are “pulled a lot of ways,” with terrorism, not illegal pharmaceuticals, as their first priority.<sup>32</sup>

Due to the huge volume of drug parcels entering the U.S. through the mail and the FDA’s limited resources, it is difficult for FDA to detain and refuse mail imports for personal use.<sup>33</sup> Consequently, tens of thousands of parcels that FDA does not review are released by Customs and sent on to their addressees, even though the products contained in these parcels may pose a health risk to consumers.<sup>34</sup> As Hubbard stated, “this is not an acceptable public health outcome.”<sup>35</sup>

The FDA’s personal use policy is not a backdoor to allow illegal importation from Canada. The Rx Depot case exemplifies that the FDA will go after those who import drugs from Canada in large quantities, while the

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<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> Mary Pat Flaherty & Gilbert M. Gaul, *Millions of Americans Look Outside the U.S. for Drugs; Desire for Low Prices Often Outweighs Obeying Law*, WASH. POST, Oct. 23, 2003, at A01.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> Hubbard, *supra* note 26.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

agency's position, as stated by Hubbard, is that the personal use policy is a threat to the public health. Yet the personal use guidelines have not been changed to reflect the agency's position. The FDA acknowledges the difficulties involved with enforcing the law against individuals who import drugs for their own use. Because of enforcement problems, the personal use policy is not effective in curtailing illegal imports.

### **The Medicine Equity and Drug Safety Act of 2000**

In 2000, the Medicine Equity and Drug Safety Act of 2000 (MEDSA) was enacted. In enacting MEDSA, Congress intended to strike a balance between protecting consumers from adulterated products cited in the 1987 law and increasing competition in the market by encouraging the resale of pharmaceuticals purchased abroad.<sup>36</sup> MEDSA provided that a new section 804 to the FDCA would take effect and allow the reimportation of certain drugs. The statutory provision would only go into effect if the Secretary of Health and Human Services could demonstrate that its implementation "would pose no additional risk to the public's health and safety ... and result in a significant reduction in the cost of covered products to the American consumer."<sup>37</sup> The statute also contained a sunset provision, which would have canceled the legal effect of the regulations five years after going into effect.<sup>38</sup>

The preamble to the legislation listed several congressional findings. These findings were:

1.

The cost of prescription drugs for Americans continues to rise at an alarming rate.

2. Millions of Americans, including Medicare beneficiaries on fixed incomes, face a daily choice between purchasing life-sustaining prescription drugs, or paying for other necessities, such as food and housing.

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<sup>36</sup>William Davis, *Comment: The Medicine Equity and Drug Safety Act of 2000: Releasing Gray Market Pharmaceuticals*, 9 TUL. J. INT'L & COMP. L. 483, 487 (2001).

<sup>37</sup>H.R. Conf. Rep. No. 106-948, at 43 (2001)(*Making Appropriations for Agriculture Rural Development, Food and Drug Administration, and Related Agencies Programs for the Fiscal Year Ending Sept. 30, 2001, and for Other Purposes*).

<sup>38</sup>*Id.*

3.

Many life-saving prescription drugs are available in countries other than the United States at substantially lower prices, even though such drugs were developed and are approved for use by patients in the United States.

4.

Many Americans travel to other countries to purchase prescription drugs because the medicines that they need are unaffordable in the United States.

5.

Americans should be able to purchase medicines at prices that are comparable to prices for such medicines in other countries, but efforts to enable such purchases should not endanger the gold standard for safety and effectiveness that has been established and maintained in the United States.<sup>39</sup>

However, neither Secretary Donna Shalala, nor her successor, Secretary Tommy Thompson, could make the demonstrations required under the act. Therefore, the MEDSA provisions never took effect. Secretary Thompson stated, “I do not believe we should sacrifice public safety for uncertain and speculative cost savings.”<sup>40</sup>

### **The Medicare Prescription Drug, Improvement, and Modernization Act of 2003**

The President signed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Act) into law on December 8, 2003. The Act includes a new Medicare prescription drug benefit, as well as provisions amending the FDCA to permit the importation of drugs from Canada under certain circumstances. The Act replaces the inoperative MEDSA section 804 with a new section 804. The Act does not repeal the existing ban on drug reimportation contained in FDCA 801(d)(1), but rather it provides a limited exception

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<sup>40</sup>Tommy Thompson, U.S. Dept. of Health and Humans Services Response to Sen. James Jeffords on Drug Reimportation, at <http://www.fda.gov/oc/po/thompson/medsact/html>.

for drug imports from Canada. Specifically, the Act states that “The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.”<sup>41</sup> There are three issues of particular interest in section 804. First, the import provisions will not take effect unless the Secretary of Health and Human Services makes a required certification. Second, imports will be permitted only if the products meet certain criteria. Third, the Act imposes obligations on manufacturers to facilitate imports.

### **1. Required Certification and Termination of Program Provisions**

Like the MEDSA provision, the new section 804 shall become effective only if the Secretary certifies to the Congress that the implementation of this section will pose no additional risk to the public’s health and safety, and result in a significant reduction in the cost of covered products to the American consumer.<sup>42</sup>

If the Secretary makes the above-mentioned certification and the FDA promulgates implementing regulations, the Act establishes a procedure in which the Secretary can halt the import program. If, after one year and before eighteen months after the effective date of the regulations, the Secretary submits to Congress a certification that “in the opinion of the Secretary, based on substantial evidence obtained after the effective date, the benefits of implementation of this section do not outweigh any detriment of implementation of this section, this section shall cease to be effective as of the date that is 30 days after the date on which the Secretary submits the certification.”<sup>43</sup>

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<sup>41</sup>FDCA § 804(b).

<sup>42</sup>FDCA § 804(l)(1).

<sup>43</sup>FDCA § 804(l)(2)(A).

Before the Secretary makes a certification to the Congress to halt the program, the Secretary must have a hearing on the record to determine the likelihood, nature, and cause of an increase in the risk to the public health and safety; whether any measures can be taken to avoid, reduce, or mitigate the increased risk; identify the benefits that would result from implementation; compare the detriment with the risks; and determine that the benefits do not outweigh the detriment.<sup>44</sup>

## **2. Requirements for Imported Drugs**

The Act applies to all prescription drugs, other than controlled substances, biological products, infused drugs (including peritoneal dialysis solutions), intravenously injected drugs, drugs that are inhaled during surgery, and parenteral drugs the Secretary determines pose a threat to the public health.<sup>45</sup> Furthermore, each imported drug must comply with section 505 of the FDCA (including being safe and effective for the intended use of the prescription drug), as well as with sections 501 and 502 of the FDCA, and other applicable requirements.<sup>46</sup> That means that the drugs must not be adulterated (section 501), misbranded (section 502), or unapproved new drugs (section 505).

The Act imposes a number of requirements. It permits imports only by pharmacists and wholesalers.<sup>47</sup> The importers must register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.<sup>48</sup> The importer must submit information and documentation to the Secretary, including the name and quantity of the active ingredient of the prescription drug; a description of the dosage form; the shipping date; the quantity shipped; the point of origin and destination of the drug; the price paid by the importer for the drug; documentation from the foreign seller specifying

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<sup>44</sup>FDCA § 804(l)(2)(B).

<sup>45</sup>FDCA § 804(a)(3).

<sup>46</sup>FDCA § 804(c)(1).

<sup>47</sup>FDCA § 804(a)(1).

<sup>48</sup>FDCA § 804(f).

the original source of the drug and the quantity of each lot of the prescription drug originally received by the seller from that source; the lot or control number of the drug; and the name, address, telephone number, and professional license number of the importer.<sup>49</sup> Also, the importer must document that the drug was statistically sampled and tested for authenticity and degradation.<sup>50</sup> The importer must certify that the drug is approved for marketing and is not adulterated or misbranded, and that it meets all labeling requirements<sup>51</sup> The importer also must provide documentation of laboratory records conducted at a qualifying laboratory ensuring that the prescription drug is in compliance with established specifications and standards.<sup>52</sup> Importation of a specific prescription drug or importation by a specific importer shall be immediately suspended by the Secretary on discovery of a pattern of importation of drugs that are counterfeit or in violation of any requirement.<sup>53</sup> The suspension continues until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported.<sup>54</sup>

The Act creates a waiver system in which individuals could import drugs for their personal use.<sup>55</sup> The Act provides that the Secretary shall issue regulations that grant individuals a waiver to permit them to import into the U.S. a ninety day supply of a prescription drug for personal use.<sup>56</sup> Under these regulations, the individual must have a valid prescription.<sup>57</sup> The import must be from a licensed pharmacy that is registered with the Secretary, and the import must be an FDA approved drug in the form of a final finished dosage that was manufactured in a registered establishment.<sup>58</sup> In addition to these regulations that the Secretary must publish, the Act also provides that the Secretary shall publish guidelines that describe the circumstances in

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<sup>49</sup>FDCA § 804(d)(1)(A) - 804(d)(1)(I).

<sup>50</sup>FDCA § 804(d)(1)(J)(III).

<sup>51</sup>FDCA § 804(d)(1)(K).

<sup>52</sup>FDCA § 804(d)(1)(L) - 804(d)(1)(M).

<sup>53</sup>FDCA § 804(g).

<sup>54</sup>*Id.*

<sup>55</sup>FDCA § 804(j).

<sup>56</sup>FDCA § 804(j)(3).

<sup>57</sup>*Id.*

<sup>58</sup>*Id.*

which the Secretary will consistently grant waivers on a case-by-case basis.<sup>59</sup>

### **3. Manufacturer Requirements**

The Act also requires pharmaceutical manufacturers to facilitate importers in certain ways. Drug manufacturers must provide importers written authorization to use the approved labeling for the prescription drug at no cost.<sup>60</sup> The manufacturer must assist in establishing that the drug complies with established specifications and standards, including the drug's authenticity and lack of degradation. The manufacturer may conduct the required quality testing itself.<sup>61</sup> If the importer performs the quality testing, the manufacturer must supply to the pharmacist or wholesaler information needed to authenticate the prescription drug being tested, as well as information needed to confirm that the labeling of the prescription drug complies with labeling requirements.<sup>62</sup>

### **4. Other Provisions**

The Act also requires the Secretary to conduct a study on the importation of drugs into the U.S. pursuant to FDCA section 804.<sup>63</sup> The Secretary shall submit findings of the study to Congress not later than twelve months after the enactment of the Act.<sup>64</sup> The Conference Report suggests that the Secretary should take into consideration the differences between biological products and drugs approved pursuant to FDCA subsection 505(b) or (j).<sup>65</sup> The Secretary also is directed to address the following issues related to drug importation:

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<sup>59</sup>FDCA §804(j)(2).

<sup>60</sup>FDCA §804(h).

<sup>61</sup>FDCA §804(e).

<sup>62</sup>*Id.*

<sup>63</sup>H.R. Conf. Rep. No. 108-391, at 660 (2003).

<sup>64</sup>*Id.*

<sup>65</sup>H.R. Conf. Rep. No. 108-391, at 833 (2003).



Identification of the limitations, including limitations in resources and in current legal authorities, that may inhibit the Secretary's ability to certify the safety of imported drugs.

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Assessment of the pharmaceutical distribution chain and the need for, and feasibility of, modifications in order to assure the safety of products that may be imported into the U.S.

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Analysis of whether anti-counterfeiting technologies could improve the safety of products in the domestic market as well as those products that could be imported.

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Estimation of costs borne by entities within the pharmaceutical distribution chain to utilize any new anti-counterfeiting technologies.

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Assessment of the scope, volume, and safety of unapproved drugs, including controlled substances, entering the United States via mail shipment.

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Determination of the extent to which foreign health agencies are willing and/or able to ensure the safety of drugs being exported from their country into the United States.

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Assessment of the potential short and long-term impacts on drug prices and prices for consumers associated with importation of pharmaceuticals from Canada and other countries into the U.S.

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Assessment of the impact on the research and development of drugs and the associated impact on consumers and patients if importation were permitted.

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Estimation of agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceutical products entering into the country.

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Identification of liability protections, if any, that should be in place, if importation is permitted, for entities within the pharmaceutical distribution chain.

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Identification of the ways in which importation could violate United States and international intellectual property rights and description of the additional legal protections and agency resources that would be needed to assure the effective enforcement of these rights.<sup>66</sup>

The Department of Health and Human Services created the Task Force on Drug Importation to conduct this study.<sup>67</sup> The task force is chaired by Surgeon General Richard H. Carmona.<sup>68</sup> It includes representatives from government agencies that “may be significantly affected by drug importation and that have significant expertise to contribute,” including the FDA, HHS’ Centers for Medicare and Medicaid Services, the Bureau of Customs and Border Protection, and the Drug Enforcement Administration.<sup>69</sup> In order to “gather and discuss information from all relevant stakeholders,” the task force intends to convene five meetings, one each with representatives from the following groups: consumer groups; professional health care groups; health care purchasers, including representatives of cities and states; industry associations; and international stakeholders.<sup>70</sup> There will also be a meeting for the general public to provide comments.<sup>71</sup> These meetings began on March 19, 2004, and will conclude on May 14, 2004.<sup>72</sup>

In discussing the goals of the task force, former FDA Commissioner Mark McClellan said, “this task force

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<sup>67</sup>U.S. Department of Health and Human Services, *Press Release: HHS Announces Task Force on Drug Importation*, Feb. 26, 2004, at [http://www.fda.gov/bbs/topics/news/2004/hhs\\_022604.html](http://www.fda.gov/bbs/topics/news/2004/hhs_022604.html).

<sup>68</sup>U.S. Department of Health and Human Services, *News Release: HHS Names Members to Task Force on Drug Importation*, March 16, 2004, at <http://www.hhs.gov/news/press/2004pres/20040316.html>.

<sup>69</sup>*HHS Announces Task Force on Drug Importation*, *supra* note 67.

<sup>70</sup>*Id.*

<sup>71</sup>*Id.*

<sup>72</sup>*HHS Names Members to Task Force on Drug Importation*, *supra* note 68.

provides an important forum for bringing all of the evidence to bear on how the public health risks created by the importation of approved drugs might be alleviated, and what the consequences for drug prices and drug innovation would be. . . It will feature extensive discussion with all stakeholders and the general public of all of the key questions involved, and it will do so in a way that allows for broad public participation.”<sup>73</sup> Secretary Thompson also made statements about the new task force. He said that while the department, under the current and previous administration, has not been able to guarantee the safety of imported drugs, the task force will look to identify new solutions that could permit safe importation.<sup>74</sup> Secretary Thompson said, The importation of drugs remains a long-standing safety concern for the Department of Health and Human Services, as we currently cannot guarantee the safety of these medicines. . . This task force will study what it would take in terms of oversight and resources to safely import drugs. It will hear from all sides of the issue in a public, transparent manner. I’m confident that it will produce a balanced picture of the costs and benefits of drug importation.<sup>75</sup>

## **5. Changes from House and Senate Proposals**

One notable provision of the Senate bill was not adopted as part of the final legislation. As introduced, the Senate bill would have prohibited discrimination against pharmacists and wholesalers that purchase prescription drugs. The bill would have barred sales by a manufacturer to pharmacists or wholesalers “on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the prescription drug.”<sup>76</sup> The bill also would have

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<sup>73</sup>*HHS Announces Task Force on Drug Importation*, *supra* note 67.

<sup>74</sup>*Id.*

<sup>75</sup>*Id.*

<sup>76</sup>S. 1, 108<sup>th</sup> Cong., § 801(a)(proposing a new FDCA § 804(i)).

prevented manufacturers from restricting the access of pharmacists or wholesalers to a prescription drug that is permitted to be imported into the United States.<sup>77</sup> This anti-discrimination provision was not enacted. Notably, however, both the Senate and House versions had the requirement of certification by the Secretary.

## **6. Comparison to MEDSA**

The language of the current Act is virtually identical to MEDSA, with some important changes. The current Act applies only to drugs imported from Canada, while MEDSA was not so limited (it provided that drugs may be imported pursuant only from a country, union, or economic area that is listed in subparagraph (A) of section 802(b)(1), or any country designated by the Secretary, subject to such limitations as the Secretary determines to be appropriate to protect the public health).<sup>78</sup> Arguably, the limitation to reimportation from Canada would enable the possibility of increased control over the process.

MEDSA contained a provision that no drug manufacturer may enter into a contract or agreement that includes a provision to prevent the sale or distribution of imported drugs.<sup>79</sup> This provision was criticized because it gave too much control to manufacturers, since it still may have been possible for manufacturers to interfere with the resale of prescription drugs back into the U.S.<sup>80</sup> For instance, manufacturers could have contracted with foreign distributors to require that they only sell back to the U.S. for a high price, or the

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<sup>77</sup>*Id.*

<sup>78</sup>FDCA § 804(f) (amended 2003).

<sup>79</sup>FDCA § 804(h) (amended 2003).

<sup>80</sup>Michele Creech, *Make a Run for the Border: Why the United States Government is Looking to the International Market for Affordable Prescription Drugs*, 15 EMORY INT'L L. REV. 593, 637 (2001).

price of the domestic counterpart.<sup>81</sup> Manufacturers could also have limited the supply to foreign countries in order to decrease their ability to resell in bulk back to the U.S.<sup>82</sup> The current Act does not contain this provision. Although the provision under MEDSA left a lot of control to the manufacturers, by removing this provision the current Act arguably gives even more control to the manufacturers to block reimportation. In the event that the Secretary makes the required certification, the current Act includes a provision that the drug manufacturer shall provide an importer written authorization for the importer to use the approved labeling for the prescription drug.<sup>83</sup> MEDSA did not contain such a provision. The original version of MEDSA required the manufacturer to provide access to FDA-approved U.S. labels, but this language was removed.<sup>84</sup> MEDSA was criticized for not having this provision, because manufacturers could block importation by denying importers access to those labels.<sup>85</sup> Therefore, if certification occurs, the current Act would take away the ability of manufacturers to block reimportation through this avenue, although it may give control back to the manufacturers by removing the provision about prohibited agreements. The waiver provisions in the current Act were also not part of MEDSA.<sup>86</sup> These provisions, which allow individuals to import prescription drugs into the U.S. for personal use, would further reduce the ability of drug manufacturers to block reimportation if the Secretary makes the required certification.

### **Likelihood of Certification By the Secretary**

As previously noted, under the current Act the Secretary of HHS must certify that its implementation

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<sup>81</sup>*Id.*

<sup>82</sup>*Id.*

<sup>83</sup>FDCA § 804(h).

<sup>84</sup>Creech, *supra* note 80, at 636.

<sup>85</sup>*Id.*

<sup>86</sup>FDCA § 804(j).

will pose no additional risk to public health and safety and will result in a significant reduction in the cost of prescription drugs to the U.S. consumer. MEDSA contained identical certification language. In December 2000, former Secretary of HHS Donna Shalala declined to implement MEDSA because of flaws in the legislation that undermine the potential for cost savings associated with prescription drug reimportation and could pose unnecessary public health risks.<sup>87</sup> In July 2001, Secretary of HHS Tommy Thompson also declined to implement MEDSA.

In a letter to Senator James Jeffords, Secretary Thompson explained his reasons for declining to make the determinations necessary to implement MEDSA. In this letter, he stated that the FDA concluded that it would be impossible to ensure that MEDSA would result in no loss of protection for the drugs supplied to the American people.<sup>88</sup> He noted that the drug distribution system in the U.S. is currently a closed system, in which most retail stores, hospitals and other outlets obtain drugs either directly from the drug manufacturers or from a small number of large wholesales. Under this system, the FDA and the states exercise oversight of every step within the chain of commercial distribution, thus generating a high degree of product potency, purity and quality.<sup>89</sup> Because only the original drug manufacturer is allowed to reimport FDA-approved drugs, safety and compliance with current law is assured.

Secretary Thompson noted that under MEDSA, the system of distribution would be opened to allow any pharmacist or wholesaler to reimport drugs from abroad, which could lead to significant growth in imported commercial drug shipments. Because the FDA and the states do not have oversight of the drug distribution

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<sup>87</sup>Robert Pear, *In a Turnaround, White House Kills Drug-Import Plan*, N.Y. TIMES, Dec. 27, 2000, at A1.

<sup>88</sup>Tommy Thompson, U.S. Dept of Health and Human Services Response to Sen. James Jeffords on Drug Reimportation, July 9, 2001, *available at* <http://www.fda.gov/oc/po/thompson/medsact.html>.

<sup>89</sup>*Id.*

chain outside the U.S., MEDSA would increase the likelihood of counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored under inappropriate and unsafe conditions reaching the American consumer.<sup>90</sup>

Secretary Thompson noted that MEDSA required chain of custody documentation and sampling and testing of imported drugs, but thought that these requirements were not a substitute for the strong protections of the current distribution system.<sup>91</sup> He stated that counterfeit, adulterated, and misbranded drugs would be difficult to detect, and the sampling and testing requirements would not identify these unsafe products entering the U.S. in large commercial shipments.<sup>92</sup> He concluded that MEDSA would create a public health risk and cause a loss of confidence in the safety of the drug supply.<sup>93</sup>

Secretary Thompson further concluded that insufficient information existed to determine that MEDSA implementation would result in significant reduction in the cost of prescription drugs to the American consumer. He stated that there are significant disincentives for reimportation under MEDSA, including the costs associated with documenting, sampling, and testing; the potential relabeling requirements and related costs and risks; the overall risk of increased legal liability; the costs associated with the management of inventories by wholesalers and pharmacists; and the risk to existing and future contractual relationships between all parties involved.<sup>94</sup> He also concluded that lower foreign prices may not translate into lower prices for U.S.

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<sup>90</sup>*Id.*

<sup>91</sup>*Id.*

<sup>92</sup>*Id.*

<sup>93</sup>*Id.*

<sup>94</sup>*Id.*

consumers, in part because of potential responses by foreign governments.<sup>95</sup>

Given the strong similarity between the current Act and MEDSA, it seems unlikely that Secretary Thompson will provide the certification required for the Act to become effective. The differences between MEDSA and the current Act, as noted before, do not address the safety and cost issues that Secretary Thompson highlighted in his letter. Instead, the changes primarily involve the amount of control drug manufacturers have to block the reimportation process. The ability, or lack thereof, of the drug manufacturers to block reimportation does not affect the underlying safety of the process. The current Act is limited to Canada, while MEDSA was not so limited. However, the fact that reimportation is limited to prescription drugs shipped from Canada does not address the safety concerns that Secretary Thompson had. Both of these changes do not address the fact that the drug distribution system would no longer be a closed system, and the FDA would not have oversight over the drugs once they entered Canada. That was the heart of Secretary Thompson's concern under MEDSA, and the current Act does nothing new to allay these concerns.

Nor does the current Act make any changes to MEDSA in regard to pricing issues. If Secretary Thompson could not guarantee significant reduction in the cost of prescription drugs to the U.S. consumer under MEDSA, there is no reason to believe that he could make this guarantee under the current Act, which has the same provisions as before.

Given the similarity between MEDSA and the current Act, I do not think the Secretary would make the required certification. The two acts are virtually the same, and not enough has changed in the intervening years to cause the Secretary to come to a different conclusion. Perhaps public opinion has grown stronger in recent years in favor of reimportation. However, there was also strong public support for reimportation at the time of the passage of MEDSA. Public opinion does not influence the safety and pricing issues that

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<sup>95</sup> *Id.*



the Secretary has been instructed to examine.

Congress knew that the Secretary would not likely make the certification required for the current Act to become effective. It enacted virtually the same language that it had enacted three years earlier, language which both Secretary Shalala and Secretary Thompson refused to enact.

Representative Dennis Moore acknowledged as much, and stated that the Act “fails to allow seniors to reimport medicine from industrialized countries where drugs are significantly cheaper. . . . [the Act] contains a provision allowing Canada-only reimportation, but [Congress] added a ‘poison pill’ requiring the Secretary of HHS to certify reimportation - something that Secretary Thompson has repeatedly said he will not do.”<sup>96</sup> Senator Thomas Daschle expressed similar sentiments about the Act: “The bottom line is we will not see any change in the current law with regard to reimportation of drugs from Canada. There is virtually a prohibition on drugs from Canada.”<sup>97</sup>

If Congress had wanted to introduce a meaningful reimportation system, it simply needed to enact a law that does not require certification by the Secretary of Health and Human Services. For example, in July 2003, the House passed the Pharmaceutical Market Access Act, a standalone measure legalizing reimportation that does not have the certification requirement.<sup>98</sup> On April 21, 2004, a bipartisan group of senators, including Senators Daschle, McCain, Dorgan, Kennedy, Snowe, and Stabenow, introduced reimportation legislation that also does not have the certification requirement.<sup>99</sup> This demonstrates that Congress knows a requirement of certification by the Secretary is fatal to reimportation legislation, yet it nevertheless included the certification language in the current Act. Legislation that bypasses the certification requirement has not

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<sup>96</sup>149 CONG. REC. E2455 (Nov. 21, 2003) (statement of Rep. Moore).

<sup>97</sup>149 CONG. REC. S15592 (Nov. 23, 2003) (statement of Sen. Daschle).

<sup>98</sup>H.R. 2427, 108<sup>th</sup> Cong. (2003).

<sup>99</sup>CONG. REC. S4228 (Apr. 21, 2004).

been enacted. Therefore, Congress purports to enact reimportation legislation in the current Act, yet knows that such legislation will not be enacted.

In order to analyze the decisions of both Secretary Shalala and Secretary Thompson not to make the necessary certifications, as well as congressional reluctance to enact meaningful reimportation legislation, it is necessary to determine whether a policy of reimportation would be beneficial to American consumers. To do so, the implications of reimportation need to be more thoroughly examined, as well as safety and pricing issues.

### **Implications of Reimportation**

A reimportation system does not make economic sense for drug manufacturers. The Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the country's leading research-based pharmaceutical and biotechnology companies, opposes reimportation. American pharmaceutical manufacturers would have no motivation to sell drugs to Canada at lower prices than they sell to the U.S. if those drugs are then sold back to the U.S., undercutting the U.S. drug market. Pharmaceutical manufacturers in the U.S. would have very little incentive to ever export their drugs to Canada. Canadian citizens would therefore have difficulties obtaining prescription drugs, and the reimportation system would not be possible.

Although the Canadian market is only a fraction of the U.S. market, if a pharmaceutical manufacturer did not want to lose the Canadian government as a customer, it would limit its shipments Canada to provide enough pharmaceuticals for Canadian citizens only. Pharmaceutical companies are currently limiting their shipments to Canada to prevent illegal reimportation to the U.S.<sup>100</sup> If a reimportation system were put into place, the pharmaceutical companies would either continue with this limiting of supply, or would stop

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<sup>100</sup>See Gaul & Flaherty, *supra* note 1; see also Bloomberg News, *Pfizer Tightens Rules on Drug Sales*, TORONTO STAR, Dec. 13, 2003, at C22.

shipping to Canada altogether.

Reimportation appears safer than importation, because the pharmaceuticals are manufactured in the U.S. However, a system of reimportation that is not closely monitored could quickly deteriorate into a system of both reimportation and importation. It would be extremely difficult to adequately monitor a reimportation system because the FDA does not have oversight over pharmaceuticals once they enter Canada. Canadian pharmacists and wholesalers who would be authorized to reimport drugs into the U.S. may ship drugs that were manufactured in foreign countries along with the U.S.-manufactured drugs. As discussed earlier, FDA and Customs are currently overwhelmed by the volume of drug parcels entering the U.S. through the mail.<sup>101</sup> Under a reimportation system, it is unlikely that chain of custody documentation, sampling and testing will be adequate to ensure the quality of every drug that enters the U.S. from Canada.<sup>102</sup> Therefore, it is likely that drugs coming from other countries and simply passing through Canada will be included in shipments of drugs “reimported” into the U.S.

A system such as this that introduced imported drugs into the U.S. would clearly undermine the entire regulatory structure of pharmaceuticals. Drugs would be entering the country that are not covered by an NDA or an ANDA, and therefore are unapproved and misbranded in violation of the FDCA. If importation became widely allowed, it is possible that the pharmaceutical companies would close their U.S. plants and would only manufacture drugs abroad to escape FDA scrutiny. Again, although the legislation previously discussed deals only with reimported drugs, it is very possible that this system would quickly deteriorate into a system that also includes imported drugs. This would lead to serious concerns for the health and safety of U.S. consumers.

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<sup>101</sup> See Hubbard, *supra* note 26.

<sup>102</sup> See Thompson, *supra* note 88.

## **Safety Concerns**

### **1.**

#### **Integrity of Products from Canada**

The FDA argues that the current “closed” system of regulation for prescription drugs provides multiple levels of protection against unsafe or ineffective drugs. This is because the FDA maintains high standards for prescription drug approval. As previously described, before the FDA approves a prescription drug, the manufacturer must demonstrate that the product is safe and effective, its labeling contains adequate directions for use, and the product is manufactured only at specific facilities that are registered with the FDA. Once the drug is approved, the manufacturer must continue to comply with GMPs to ensure that the quality of the product is evaluated throughout the manufacturing process. The pharmacists and wholesalers who sell or distribute prescription drugs must be licensed or authorized by the states in which they operate.<sup>103</sup>

In addition, there are limited channels of entry into the U.S. drug supply. Prescription drugs generally arrive either directly from a manufacturing facility that meets FDA requirements or from a U.S. wholesaler who receives the drug from an FDA approved manufacturing facility. Therefore, the FDA and the states can exercise oversight of every step within the commercial drug distribution chain from manufacture to sale. The only exception is when the U.S. manufacturer reimports its own product, and even in this instance the manufacturer must possess documentation that the product is authentic, has been properly handled, and is relabeled for the U.S. market. Therefore, under this “closed” system, there is a high degree of the product’s quality assurance.<sup>104</sup>

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<sup>103</sup>Tommy Thompson, U.S. Dept. of Health and Human Services Response to Sen. James Jeffords on Drug Reimportation, Attachment A: Assessment of the Potential for Health Risk to U.S. Consumers Under the Medicine Equity and Drug Safety Act of 2000, July 9, 2001, *available at* <http://www.fda.gov/oc/po/thompson/medsact.html>.

<sup>104</sup>*Id.*

The FDA asserts that since the passage of the Prescription Drug Marketing Act of 1987, there have been few incidents of counterfeit prescription drugs entering the U.S. distribution chain from abroad.<sup>105</sup> Yet there have been numerous reports of increased counterfeiting around the world, perhaps reflecting the financial incentives to do so.<sup>106</sup> The FDA believes that American consumers have been protected from most counterfeit and dangerous drugs because of the strong oversight of the distribution system.<sup>107</sup> A system of reimportation would disrupt the oversight of this system because foreign pharmacies and wholesalers are not subject to FDA or state oversight.

Under a system of reimportation, there are numerous reasons why the integrity and safety of prescription drugs coming into the U.S. cannot be assured. For example, under the current Act, as under MEDSA, there is no requirement to document the chain of custody for products coming from other than the first foreign recipient. Instead the acts rely entirely on product testing.<sup>108</sup> The FDA believes that “it is arguably more important to have a chain of custody requirement for products that change hands multiple times.”<sup>109</sup> A chain of custody requirement could enable more oversight and control over the reimportation process.

However, even if new reimportation legislation contained the additional safeguard of chain of custody requirements it would be of limited value as a safety measure because documentation can be falsified. The FDA would have difficulty inspecting foreign traders to ensure that such documentation is true and accurate.<sup>110</sup> Therefore, because of the limited value of chain of custody documentation, it could be argued that requiring it would be a needless waste of time and expense. The sampling and testing procedures that are in the current Act would provide a more productive means of assuring product integrity.

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<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> See FDCA § 804(d)(1)(J)(ii).

<sup>109</sup> Thompson, *supra* note 105.

<sup>110</sup> *Id.*

However, the sampling and testing procedures that are proposed would not detect all potential counterfeit or substandard drug products. The FDA states that “an enormous battery of prohibitively expensive tests” would have to be performed in order to ensure that the drugs are authentic and are not adulterated.<sup>111</sup> Also, because the FDA would not be able to test entire shipments, counterfeit or substandard drugs may avoid detection by being commingled with acceptable drugs. For example, certain lots of drugs may be stored under unacceptable conditions while in the foreign country, resulting in some products that meet requirements and some products that do not. The portion that is sampled and tested may meet the specifications, and the whole shipment would be imported to the U.S., including the substandard products. Therefore, the FDA takes the position that end-product testing cannot substitute for in-process controls.<sup>112</sup>

It could be argued that there are in-process controls for pharmaceuticals in Canada. At the request of the Governor of Illinois, a report was prepared on the feasibility and safety of purchasing prescription drugs from Canadian pharmacies. This report was not limited to reimportation, but rather deals with both reimported and imported drugs. As discussed previously, the issues involved overlap significantly. This report found that drugs can be safely purchased from Canada.<sup>113</sup> It concluded that though not identical in statutory or regulatory text, methods of ensuring safety and efficacy of prescription drugs are comparable in Canada and the U.S.<sup>114</sup> It also found that the provincial regulatory systems in Manitoba and Ontario (the two provinces studied) provide substantially equivalent protection for the health and safety of the public as is provided for in Illinois.<sup>115</sup> As will be discussed below, the FDA strongly criticized this report, stating that the report’s

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<sup>111</sup>*Id.*

<sup>112</sup>*Id.*

<sup>113</sup>Ram Kamath & Scott McKibbin, *Report on Feasibility of Employees and Retiree Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies*, Office of Special Advocate for Prescription Drugs, Illinois Department of Central Management Services, Oct. 27, 2003, available at <http://www.affordabledrugs.il.gov/pdf/SpecialAdvocateCanadian10-27-03Final.pdf>.

<sup>114</sup>*Id.* at 2.

<sup>115</sup>*Id.*

“proposal for ‘buyer beware’ drugs simply doesn’t achieve the key goals of affordability and safety.”<sup>116</sup>

One reason cited by the Illinois report for its conclusions is that Canada’s system for the pricing of pharmaceuticals is less likely than that of the system in the United States to foster drug counterfeiting.<sup>117</sup> In Canada, the price of prescription drugs is essentially the same across all classes of trade. This is because the Canadian government negotiates drug prices as a part of the approval process. The wholesalers acquire the drug at this negotiated price, and the drug is then sold to the retailers at a small premium.<sup>118</sup> In contrast, in the United States, the cost of a drug may vary by the retailer, class of trade, negotiated price, or location.<sup>119</sup> For instance, the price paid for the same drug by a not-for-profit hospital may be significantly different from the price paid by a retail pharmacy. As a result of this high variability in price, a secondary market has developed that creates situations where a chain of custody cannot be established.<sup>120</sup> The complexity and multiplicity of pricing arrangements in the U.S. can create opportunities for diversion and counterfeiting.

Despite the report’s assertions, counterfeiting is also a threat in Canada. A number of counterfeiting cases are under investigation with the Royal Canadian Mounted Police.<sup>121</sup> Also, an importation plan could encourage counterfeiters to increasingly use Canada as an entry point for the U.S. market.<sup>122</sup> Therefore, the asserted lack of counterfeit drugs in Canada does not establish that the purchase of prescription drugs from Canada would be safe.

The Illinois report also pointed to the distribution system in Canada as another reason why purchasing prescription drugs from Canada would be safe. Medications dispensed in Canada are mainly in “unit-of- use”

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<sup>116</sup>Letter from William Hubbard to Dr. Kamath and Mr. McKibbon, Nov. 6, 2003, at [www.fda.gov/oc/opacom/hottopics/importdrugs/kamath.html](http://www.fda.gov/oc/opacom/hottopics/importdrugs/kamath.html).

<sup>117</sup>Kamath & McKibon, *supra* note 113, at 2.

<sup>118</sup>*Id.* at 13.

<sup>119</sup>*Id.*

<sup>120</sup>*Id.*

<sup>121</sup>Hubbard, *supra* note 116.

<sup>122</sup>*Id.*

sealed packages, shipped directly from the manufacturer.<sup>123</sup> The report asserts that manufacturer sealed, unit-of-use packages dramatically reduce the possibility of medication errors and counterfeiting.<sup>124</sup> The FDA agrees that true unit-of-use packages may help deter counterfeiters.<sup>125</sup> However, FDA surveys of the actual drugs mailed to Americans from Canada have found that very few are in true unit-of-use containers. Rather, the drugs tend to be in the manufacturer’s “stock” bottles, which tend to come in specific large volume amounts (e.g., 100 tablets).<sup>126</sup> These bottles are not intended to be used by individual patients whose prescriptions are for more or less than 100 units.<sup>127</sup> Moreover, they do not generally include appropriate labeling and warnings for patients.<sup>128</sup> Therefore, medication errors can actually be encouraged, and many patients may be getting larger quantities than their doctors are prescribing.

Another reason cited by the Illinois report for why it is safe to purchase drugs from Canada is that Canadian law, like U.S. law, requires pharmaceutical companies to comply with Good Manufacturing Practices (GMPs).<sup>129</sup> Brand name drugs sold in Canada that are manufactured in the United States are manufactured in FDA approved facilities.<sup>130</sup> Other brand name drugs that are not manufactured in the United States are manufactured in facilities approved by Health Canada’s Therapeutic Product Directorate.<sup>131</sup> Although Canada also requires GMPs, the requirements in Canada are different than those in the U.S.<sup>132</sup>

The pharmaceutical manufacturing, storage, distribution and dispensing requirements under Canadian law

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<sup>123</sup>Kamath & McKibon, *supra* note 113, at 2.

<sup>124</sup>*Id.*

<sup>125</sup>Hubbard, *supra* note 116.

<sup>126</sup>*Id.*

<sup>127</sup>*Id.*

<sup>128</sup>*Id.*

<sup>129</sup>Kamath & McKibon, *supra* note 113, at 2.

<sup>130</sup>*Id.*

<sup>131</sup>*Id.* at 13-14.

<sup>132</sup>*See id.* at 43-69.



are substantially equivalent to those requirements in the U.S.<sup>133</sup> Both countries require quality control units to test and inspect the product and its packaging. In Canada, every fabricator, packager/labeler, distributor and importer has on their premises in Canada a quality control unit which has the authority to approve or reject drug products which are manufactured, processed, packed or held.<sup>134</sup> These units have the responsibility of checking or testing all drugs in their control for identity, strength, quality and purity of the pharmaceuticals.<sup>135</sup> These units are also responsible for ensuring that proper storage and transportation conditions of the pharmaceuticals are met.<sup>136</sup> This includes proper temperature, humidity, lighting controls, stock rotation, sanitation, and any other precautions necessary to maintain the quality and safe distribution of the drug.<sup>137</sup>

The manufacturing control requirements are also substantially similar in both countries.<sup>138</sup> Canada requires written procedures for production and process controls to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.<sup>139</sup> There are requirements to assure that the correct labeling and packaging materials are used in drug products.<sup>140</sup> Labeling requirements include information on temperature, humidity, light and other proper storage procedures, as well as the expiration date.<sup>141</sup> However, these labeling requirements are different than the U.S. labeling requirements. The FDA states that drugs imported from Canada virtually never have the FDA-approved U.S. labeling, which is designed to inform patients about the drug's proper use and to give warning about particular

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<sup>133</sup>*Id.* at 3.

<sup>134</sup>*Id.* at 43.

<sup>135</sup>*Id.* at 38.

<sup>136</sup>*Id.*

<sup>137</sup>*Id.*

<sup>138</sup>*Id.* at 40.

<sup>139</sup>*Id.*

<sup>140</sup>*Id.*

<sup>141</sup>*Id.*

dangers inherent in the drug.<sup>142</sup> The Canadian labels are lacking the usage information and warnings.

Both countries have regulations for the premises where pharmaceuticals are to be manufactured, processed, packed, or held, which require that they be maintained in a clean and sanitary condition.<sup>143</sup> The two countries also have similar building design and construction requirements, as well as ventilation, air filtration, heating, cooling and sanitation requirements.<sup>144</sup> These requirements include segregation of production and non-production areas. There are further requirements for the segregation of pharmaceuticals and components which have been tested and approved from those which have not.<sup>145</sup> Sanitation and cleaning requirements are substantially equivalent.<sup>146</sup>

Like the U.S., Canada requires that records be kept on virtually every aspect of pharmaceutical production: raw material testing, finished product testing, container testing, label verification, sanitation and storage, and the ultimate destination of the pharmaceutical.<sup>147</sup>

Despite the similarities in regulations between the two countries, the degree of enforcement of the regulation varies. Enforcement of GMPs in the U.S. is very strong. For example, in May of 2002, Schering-Plough signed a consent decree with the FDA in which they were enjoined from manufacturing drugs at two facilities in New Jersey and two facilities in Puerto Rico until they demonstrated compliance with current GMPs.<sup>148</sup> Schering-Plough also agreed to pay \$500 million in fines.<sup>149</sup> Similarly, Wyeth Labs signed a consent decree of permanent injunction in 2000 in which Wyeth agreed to a series of measures aimed at ensuring that two of

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<sup>142</sup>Hubbard, *supra* note 116.

<sup>143</sup>Kamath & McKibon, *supra* note 113, at 39.

<sup>144</sup>*Id.*

<sup>145</sup>*Id.*

<sup>146</sup>*Id.*

<sup>147</sup>*Id.* at 40-41.

<sup>148</sup>Schering-Plough - FDA Consent Decree (D. N.J., May 20, 2002)(No. 02-2397), available at [http://www.fda.gov/cder/dmpq/SP\\_consent\\_decree.htm](http://www.fda.gov/cder/dmpq/SP_consent_decree.htm).

<sup>149</sup>*Id.*

its manufacturing facilities were in compliance with GMP regulations.<sup>150</sup> Wyeth also agreed to pay up to \$35 million in fines.<sup>151</sup> Abbott Labs signed a consent decree of permanent injunction in 1999 in which it agreed to stop manufacturing and distributing many of its in-vitro diagnostic tests until it corrected manufacturing problems.<sup>152</sup> Abbot Labs agreed to pay \$100 million to the U.S. Treasury, plus additional fines up to \$10 million. These consent decrees show that enforcement of GMPs in the U.S. is very strict, and can cost the pharmaceutical companies up to half a billion dollar of fines if they do not comply. In contrast, enforcement of regulations in Canada is very weak. If regulations are not enforced, they become meaningless.

The report from the Governor's Office of Illinois also looked at pharmacy practice, and found that pharmacy practice in the Canadian provinces of Manitoba and Ontario is equal to or superior to pharmacy practice in Illinois.<sup>153</sup> The educational requirements and professional regulation of licensed pharmacists in the two Canadian provinces are as rigorous as those of Illinois.<sup>154</sup> Furthermore, incident reporting of internal process errors was more rigorous in Manitoba and Ontario than in Illinois.<sup>155</sup>

This all seems to suggest that pharmaceuticals bought in Canadian pharmacies by Canadian residents are safe and effective. The FDA has often noted that Canadian health authorities set high standards for drugs sold to their citizens.<sup>156</sup> However, this does not mean that a system of reimportation would also be safe and effective. If a company is selling drugs only for export to the United States, and not to Canadian citizens, Health Canada does not regulate the drugs or the company at all.<sup>157</sup> Canadian law exempts pharmaceuticals intended for export from any regulatory oversight. Section 37 of the Canadian Good and Drugs Act states, "This Act does not apply to any packaged food, drug, cosmetic, or device, not manufactured for consumption

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<sup>150</sup>FDA Talk Paper, *Wyeth-Ayerst Laboratories Signs Consent Decree with FDA*, Oct. 3, 2000, available at <http://www.fda.gov/bbs/topics/ANSWERS/ANS01041.html>.

<sup>151</sup>*Id.*

<sup>152</sup>HHS News, *Abbot Labs Signs Consent Decree with FDA; Agrees to Correct Manufacturing Deficiencies*, available at <http://www.fda.gov/bbs/topics/NEWS/NEW00697.html>

<sup>153</sup>Kamath & McKibon, *supra* note 113, at 2.

<sup>154</sup>*Id.*

<sup>155</sup>*Id.* at 3.

<sup>156</sup>Hubbard, *supra* note 116.

<sup>157</sup>*Imported Drugs Raise Safety Concerns*, *supra* note 17.

in Canada and not sold for consumption in Canada. . . .” Therefore, the drugs coming into the U.S. would be monitored neither by the FDA nor Health Canada.

Although there currently are many pharmaceuticals crossing the border, if reimportation were legalized and institutionalized the amount of pharmaceuticals going into the U.S. would increase dramatically. If this were to happen, the drug supply in Canada could change. Drug counterfeiting in Canada could increase because of the profit to be made by selling drugs to the U.S. These counterfeit drugs entering the U.S. would be injurious to the health and safety of American consumers. If reimportation were institutionalized, drugs could be stored incorrectly as they are transported into the U.S. and would become ineffective and unsafe. Testing, storage, and record-keeping requirements could address these problems. But as explained earlier, testing and record-keeping requirements may not be adequate to ensure drug safety. The fact that drugs currently sold in Canada are safe does not mean that they will remain safe if a system of reimportation were instituted.

However, this could also work the other way, and instead support a tightly monitored system where only drugs that were originally manufactured in the U.S. are reimported back into the country. People currently buy drugs from Canada although it is illegal. These people run the risk that they are buying drugs from a company that is not monitored by Health Canada and that imports its drugs from other countries. Therefore, a regulated system of reimportation could be beneficial to protect those people who are currently buying drugs from Canada.

## **2. Counterfeit Drugs**

The challenge of protecting against unsafe counterfeit drugs has recently become more difficult. Although drug counterfeiting is a relatively rare event in this country, the FDA has seen its counterfeit drug investigations increase to over twenty per year since 2000.<sup>158</sup> This is a sharp increase from the average of only about five per year through the late 1990s.<sup>159</sup> In recent years counterfeiting has shifted increasingly into “finished” pharmaceuticals (the final product taken by the patient) as opposed to the counterfeiting of “bulk” drug ingredients in the past.<sup>160</sup>

To illustrate the recent incidences of counterfeiting, on May 21, 2003, the U.S. Attorney’s Office for the Southern District of Florida filed charges against three individuals for the unlawful sale and wholesale distribution of counterfeit versions of Procrit, a medication indicated mainly to help cancer, anemia, and HIV patients increase their red blood cell count. The vials distributed did not contain any active ingredient for Procrit, but instead contained only bacteria-tainted water.<sup>161</sup> All three defendants pleaded guilty. In another example, on May 23, 2003, the FDA issued an alert on a counterfeit version of Lipitor, a drug used to decrease cholesterol.<sup>162</sup> The FDA is investigating this case, but it appears that some of the counterfeit product originated from overseas.<sup>163</sup>

The FDA believes the increase and shift in counterfeiting has occurred for a number of reasons. One reason is that better counterfeiting technology exists, including improved technology to make labeling, packaging, and products that appear real.<sup>164</sup> Another is that there exist better organized and more effective criminal groups who are attracted by financial opportunities.<sup>165</sup> Use by unlicensed pharmacies and foreign websites

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<sup>158</sup>FDA, *New FDA Initiative to Combat Counterfeit Drugs*, at <http://www.fda.gov/oc/initiatives/counterfeit/background.html>.

<sup>159</sup>*Id.*

<sup>160</sup>*Id.*

<sup>161</sup>Taylor, *supra* note 14

<sup>162</sup>*Id.*

<sup>163</sup>*Id.*

<sup>164</sup>*Id.*

<sup>165</sup>*Id.*

of the Internet as a sales tool also contributed to the increase in counterfeiting.<sup>166</sup> There are also weak spots in the domestic wholesale drug distribution chain, including some wholesalers who acquire most of their inventory from secondary sources, that do not maintain effective due diligence efforts on these sources and ignore warning signs of illegal behavior.<sup>167</sup>

This increase in counterfeiting activity has important ramifications for a reimportation system. While the current “closed” system of drug distribution in the U.S. may be effective at protecting U.S. drug consumers, it is not foolproof. Counterfeiting activity currently occurs in the U.S., and one could argue that a tightly controlled reimportation system would be no more dangerous than the current system. As discussed earlier however, a reimportation system would produce less control and oversight over the drug distribution system. It therefore seems unlikely that a system of reimportation would prevent counterfeiting activity. Counterfeiting is a profitable activity that is occurring and is on the rise. If counterfeiting activity occurs under a system that is currently tightly controlled, it is almost sure to happen in a reimportation system that by default is less closely monitored. The Lipitor incident may be an example of the inability to adequately examine drugs imported from abroad. If this is true, then under a system of reimportation, where even more drugs are imported from abroad, Customs agents may be even less likely to detect unsafe drug products. This increase in counterfeiting activity provides an argument against a system of reimportation.

### **3. Internet and Mail Order Sales**

The Internet is transforming the way people live, and the way many people buy prescription drugs. Sales of prescription drugs over the Internet have increased rapidly in recent years. Many reputable Internet phar-

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<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

macies provide consumers seeking prescription drugs with a measure of safety, privacy and convenience.<sup>168</sup> Prescription drug sales over the Internet can provide tremendous benefits to consumers, including access to drugs for the disabled or otherwise homebound, for whom a trip to the pharmacy can be difficult; the convenience of shopping 24 hours a day; a complete selection of pharmaceutical products; and privacy for those who don't want to discuss their medical needs in a public place.<sup>169</sup> However, the Internet also has created a marketplace for the sale of unapproved new drugs, prescription drugs dispensed without a valid prescription, and products marketed with fraudulent health claims.<sup>170</sup> In many cases, the FDA cannot provide consumers with any assurance that the drugs purchased over the Internet were manufactured under current GMP requirements.<sup>171</sup> The sites that are unlicensed or otherwise engaged in the illegal reimportation or importation of prescription drugs not only violate the FDCA, but also pose a serious potential threat to the health and safety of American citizens.

This problem is exacerbated because Internet sales of prescription drugs have become a lucrative business. One Internet pharmacy, the Canadian Drugstore, or [www.tcds.com](http://www.tcds.com), has \$55 million in annual sales.<sup>172</sup> Another Internet pharmacy, CanadaDrugs.com, has annual sales of \$100 million.<sup>173</sup> These are but two of the approximately 120 Canadian online pharmacies selling about \$700 million worth of prescription drugs each year to Americans.<sup>174</sup> Based on a 2000 survey, there were between 300 and 400 Internet sites selling prescription drugs to consumers, with approximately half located domestically, and half located outside the U.S.<sup>175</sup>

In January of 2003, Glaxo, the world's second largest pharmaceutical maker, announced that it would curtail

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<sup>168</sup> *International Prescription Drug Parity: Are Americans Being Protected or Gouged? Before the Subcommittee on Human Rights and Wellness, House Committee on Government Reform*, 108<sup>th</sup> Cong. (Apr. 3, 2003)(statement of William Hubbard), available at <http://www.fda.gov/ola/2003/internetsales0403.html>.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*

<sup>172</sup> Gaul & Flaherty, *supra* note 1.

<sup>173</sup> *Id.*

<sup>174</sup> *Id.*

<sup>175</sup> *Examining Prescription Drug Reimportation: A Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs, Before the Subcommittee on Health of the House Committee on Energy Commerce*, 107<sup>th</sup> Cong. (Jul. 25, 2002)(statement of William Hubbard), available at <http://www.energycommerce.house.gov/107/hearings/07252002Hearing677/Hubbard1147print.htm>.

shipments to Canadian wholesalers supplying the Internet pharmacies.<sup>176</sup> Pfizer, the world's largest manufacturer, has stiffened restrictions on sales of its products to Canadian pharmacies to limit cross-border sales.<sup>177</sup> Several other companies have followed suit. The Internet operators have turned to loose networks of pharmacies scattered across Canada to augment their supplies.<sup>178</sup>

The owner of CanadaDrugs.com stated that he and his colleagues know that they are violating U.S. law. "We're completely aware," he said. "We've been aware from when we started. From our perspective, it's legal because American authorities aren't enforcing the strict reading of FDA regulations."<sup>179</sup>

Recently the FDA has initiated criminal and civil cases against Internet pharmacies. With respect to Internet drug sales, the FDA has initiated the following actions: 372 Internet drug criminal investigations; 150 Internet-related drug arrests, 60 involving Internet pharmacies; 102 convictions, with 34 convictions involving Internet pharmacy cases; 95 open Internet drug criminal investigations; 90 sites under active review for possible regulatory or civil action; nearly 200 cyber warning letters sent to domestic and foreign online sellers; 5 preliminary injunctions; 15 product seizures; and 11 product recalls.<sup>180</sup> The FDA believes that these figures provide insight into the seriousness of the risks these products pose to the public health.<sup>181</sup>

One reason that Internet sales are so dangerous, in addition to the safety concerns with reimported drugs in general, is that many Internet sites provide prescription drugs by having consumers fill out a questionnaire

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<sup>176</sup>Gaul & Flaherty, *supra* note 1.

<sup>177</sup>Bloomberg News, *supra* note 100.

<sup>178</sup>Gaul & Flaherty, *supra* note 1.

<sup>179</sup>*Id.*

<sup>180</sup>*A System Overwhelmed: The Avalanche of Imported, Counterfeit and Unapproved Drugs in the U.S., Before the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, 108<sup>th</sup> Cong. (June 24, 2003)*(statement of William Hubbard & John M. Taylor), available at <http://www.fda.gov/ola/2003/importedrx0624.html>.

<sup>181</sup>*Id.*



rather than seeing a doctor.<sup>182</sup> This can pose serious health risks, because a questionnaire generally does not provide sufficient information for a healthcare professional to determine if that drug is appropriate or safe to use, if another treatment is more appropriate, or if the consumer has an underlying medical condition where using that drug may be harmful.<sup>183</sup> The health risks are even more pronounced given that in recent years many more drugs require “risk management” programs and regular monitoring to ensure they are used safely and effectively.<sup>184</sup> Many drugs have especially complex manufacturing and storage requirements.<sup>185</sup> The public health safeguards that the FDA has imposed are being undermined by the illegal importation of these products.<sup>186</sup>

In the summer of 2003, the FDA and the Bureau of Customs and Border Patrol conducted a series of blitz examinations on mail shipments of foreign drugs destined for U.S. consumers. These blitz exams were conducted in Miami, New York, San Francisco, and Carson, California mail facilities. These exams showed that many foreign drug products are of unknown quality or origin, have not been approved in the U.S., and may pose potentially serious safety concerns.<sup>187</sup> Of the drug products examined, 15.8% entered the U.S. from Canada. Overall, 88% of the imported drug products examined contained unapproved drugs.<sup>188</sup>

In addition to the import blitz exams, the FDA conducted an informal study to screen and examine mail-entry drug samples from foreign countries during a six-week period in early summer 2003. The FDA reviewed 154 entries from Canada representing 350 drug items. The study found that it was not possible to verify where, or under what conditions, the drugs were manufactured for any of the pharmaceutical products that

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<sup>182</sup>Hubbard, *supra* note 175.

<sup>183</sup>*Id.*

<sup>184</sup>Taylor, *supra* note 14.

<sup>185</sup>*Id.*

<sup>186</sup>*Id.*

<sup>187</sup>*Id.*

<sup>188</sup>*Id.*

were offered.<sup>189</sup> For those drugs that were ordered from websites, the need for a valid prescription was not always specified, and if the site identified a prescription requirement, it did not always disqualify prescriptions coming from other countries.<sup>190</sup>

The import blitz exams and the mail-entry studies should give us pause about implementing a system of reimportation. Many of the drugs entering the U.S. in these studies did not originate from the U.S, and therefore are not reimported. Yet under a system of reimportation, many websites offering drugs from Canada would presumably become legal. This could hasten the aforementioned disintegration of the reimportation/importation distinction, as websites that offer both imported and reimported drugs for sale in the U.S. would be difficult to control.

The increased use of Internet and mail order sales of prescription drugs demonstrate weakness in the current drug distribution system in the U.S. Consumers are looking to buy less expensive prescription drugs than they find on their pharmacy shelves. However, consumers are often risking their health and safety by purchasing drugs from certain Internet and mail order sites. The FDA does not have the resources to examine every drug that is shipped to the U.S. from abroad. If a reimportation system were implemented in the U.S., there would be even more drugs entering this country from abroad, and the FDA would not have the resources to inspect every parcel. This would increase the risk to U.S. consumers. A reimportation system would also put some controls in place over drugs that are entering the U.S. from abroad. These controls are not currently in place because it is contrary to the law. These controls may or may not provide more protection to individuals who are currently buying prescription drugs from Internet pharmacies and putting themselves

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<sup>189</sup>*Id.*

<sup>190</sup>*Id.*

at risk.

### **Factors that Affect Prescription Drug Prices in the U.S.**

At its core, the reason for the desire to implement reimportation legislation is the high cost of prescription drugs. Proponents of reimportation assert that reimportation will reduce prescription drug prices. It is widely accepted that prescription drugs cost too much in the United States.<sup>191</sup> A recent compilation of U.S. and Canadian drug-price comparisons showed that, on average, prices charged in the United States were about 70% higher than prices in Canada.<sup>192</sup> The average retail price of a brand name prescription drug was \$71.18 in 2001, which was a 9% increase from 2000, and a 162% increase from 1990.<sup>193</sup> The average retail price of a generic prescription drug was \$21.96 in 2001, which was a 14% increase from 2000, and a 113% increase from 1990.<sup>194</sup> It is this high cost of prescription drugs in the U.S., and the comparatively lower prices of prescription drugs in Canada, that leads to the controversy over reimportation. Experts blame the high cost of prescription drugs in the U.S. on an array of factors.

#### **1. Research and Development**

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<sup>191</sup> But see Dr. Merrill Matthews Jr., *Prescription Drug Prices and Profits*, Institute for Policy Innovation (Jan. 9, 2003), at <http://www.ipi.org>. Matthews states that the average prescription drug costs about \$50. He compares this with the price of a family of four going to the movies (\$25 for admission, \$25 for refreshments), or the price of a motel for one night (\$50 for a moderately priced motel, \$150-\$200 a night for a better hotel). He argues that people regularly and voluntarily spends as much or more money than they do on prescription drugs on thing that they want and think nothing of it, even though surely the prescription drug is worth as much as a night at the movies. However, this argument compares discretionary expenses with necessary life-saving drugs. It also ignores the fact that the cost of prescription drugs are critical to seniors, many of whom are on a fixed budget and do not have the opportunity for discretionary spending.

<sup>192</sup> *Drug Importation Policy: Current Laws and Issues for Debate*, *supra* note 12.

<sup>193</sup> Kaiser Family Foundation, *Issue spotlight: Prescription Drugs Facts at a Glance*, at [http://www.kaisernetwork.org/static/spotlight\\_rxdugs\\_facts.cfm](http://www.kaisernetwork.org/static/spotlight_rxdugs_facts.cfm).

<sup>194</sup> *Id.*

One reason cited for the high price of prescription drugs is to enable the drug companies to recoup the billions of dollars invested in research and development. The process of bringing a new drug to market is long and complex. Research and development costs include discovery and preclinical costs, clinical costs, clinical trial success and failure rates, the impact of long development times on investment costs and increased costs of capital, and the expenses of failed projects.<sup>195</sup> It takes an average of ten to fifteen years to develop a new drug, from the laboratory to FDA approval.<sup>196</sup> The development of new drugs is a very risky process. Of 5,000 – 10,000 screened compounds, only 250 enter preclinical testing, five enter clinical testing, and only one is approved by the FDA.<sup>197</sup>

Because of the length and complexity of R&D, the average cost of developing a new medicine has grown from \$138 million in 1975 to \$802 million in 2000.<sup>198</sup> PhRMA companies spent a total of \$32 billion on R&D in 2002.<sup>199</sup> This is more than triple the industry investment in R&D in 1990.<sup>200</sup> In 1977, the industry spent \$1.3 billion on total R&D.<sup>201</sup> Given the high cost of R&D, full commercial success is available only for a minority of products. Only three of ten marketed drugs produce revenues that match or exceed average R&D costs.<sup>202</sup> To sustain the high costs the successful medicines must cover the cost of the unsuccessful ones. The industry claims that a decrease in pricing would result in reduced profits, which would reduce R&D investment, and therefore slow drug innovation and harm the American consumer.<sup>203</sup> This would risk

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<sup>195</sup>Pharmaceutical Research and Manufacturers' Association, *Insights: Highlights from the Pharmaceutical Industry Profile 2003*, available at <http://www.phrma.org/publications/publications//2003-10-07.892.pdf>.

<sup>196</sup>*Id.* (based on data from Center for the Study of Drug Development, Tufts University, 1995).

<sup>197</sup>*Id.*

<sup>198</sup>*Id.* (citing J. A. DiMasi, R. W. Hansen, and H. G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151-85 (2003)).

<sup>199</sup>*Id.* (citing PhRMA Annual Membership Survey, 2003).

<sup>200</sup>Pharmaceutical Research and Manufacturers' Association, *Pharmaceutical Industry Profile 2003*, at 10, (2003), available at <http://www.phrma.org>.

<sup>201</sup>*Id.*

<sup>202</sup>*Id.* (citing H. Grabowski, J. Vernon, and J. DiMasi, *Returns on Research and Development for 1990s New Drug Introductions*, 20 PHARMACOECONOMICS SUPPL. 3, 11-29 (2002)).

<sup>203</sup>Andrew Sullivan, *The Way We Live Now: ProPharma*, N.Y. TIMES MAGAZINE, Oct. 29, 2000, at 21.

ending “the greatest era in research in memory.”<sup>204</sup>

It is indisputable that the development and manufacturing of new drugs is a lengthy and expensive process. However, drug companies on average spent only 11% of total revenue on R&D.<sup>205</sup> This number is arguably inconsistent with the pharmaceutical industry’s claim that the main cause for the high cost of prescription drugs is the amount of capital spent on R&D.<sup>206</sup> However, the pharmaceutical industry would point out that it spends 18.2% of domestic sales on R&D inside the United States.<sup>207</sup> This means that the pharmaceutical industry invests a greater percentage of sales in research than other American industries, including the electronics, communications, and aerospace sectors.<sup>208</sup> On average, a PhRMA company’s R&D to sales ratio is higher each year than those of Microsoft, Boeing, and IBM.<sup>209</sup> However, one can argue the relative importance of R&D, both economically and socially, in each of the industries.

The pharmaceutical industry is not paying for the cost of R&D alone. The federal government makes considerable investments in pharmaceutical R&D, contributing more than 55% of the total amount spent.<sup>210</sup> The National Institutes of Health (NIH) is a taxpayer-funded federal research institute that invests considerable money in R&D.<sup>211</sup> In 2000, the NIH spent \$17.6 billion in taxpayer funds on biomedical R&D alone.<sup>212</sup> Overall, the NIH funds almost 40% of all medical R&D.<sup>213</sup> Because so much R&D is funded by the gov-

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<sup>204</sup>*Id.*

<sup>205</sup>Families USA Foundation, *Profiting from Pain: Where Prescription Drug Dollars Go*, at 10 (Jul. 2002), available at <http://www.familiesusa.org>.

<sup>206</sup>Farin Khosravi, *Price Discrimination in the United States: Why are Pharmaceuticals Cheaper in Canada and Are Americans Seizing the Opportunities Across the Border?*, 9-SPG L. & BUS. REV. AM. 427, 429-30 (2003).

<sup>207</sup>Pharmaceutical Research and Manufacturers’ Association, *supra* note 200, at 10.

<sup>208</sup>*Id.* at 11 (citing PriceWaterhouseCoopers, *The Critical Roles of R&D in the Development of New Drugs*, Washington, D.C.: PWC, 2001).

<sup>209</sup>*Id.*

<sup>210</sup>Creech, *supra* note 80, at 601-02.

<sup>211</sup>*Id.* at 602.

<sup>212</sup>*Id.*

<sup>213</sup>*Id.*

ernment, it can be argued that a decrease in the pharmaceutical industry's profits will not severely hamper R&D funding.

The pharmaceutical industry downplays the importance of government funding. It points out that it spends more on R&D than the total NIH operating budget of \$24 billion, only part of which is devoted to pharmaceutical research.<sup>214</sup> The pharmaceutical industry states that only four of forty-seven drugs with U.S. sales of \$500 million a year had been developed in part with technologies created with NIH funding, and it is virtually impossible to determine direct governmental contributions to any final therapeutic product.<sup>215</sup> The pharmaceutical industry states that the collaboration between private and publicly funded research is one of the reasons the U.S. has surpassed Europe as the leader in pharmaceutical R&D and is responsible for many medical advances.<sup>216</sup>

Yet the government funds R&D in other ways. The drug industry benefits from several federal tax breaks, some of which encourage research by allowing companies to deduct qualified research expenses and receive research and experimentation tax credits.<sup>217</sup> There are no publicly available data showing the exact amount of tax relief the industry receives for its investment in research.<sup>218</sup> The industry has lobbied hard for R&D tax credits, and the total amount of tax credits lowered the industry's effective tax rate from 35.2% to 17.1%.<sup>219</sup> The tax credits and deductions supplied by the government because of R&D lessen the argument

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<sup>214</sup>Pharmaceutical Research and Manufacturers' Association, *supra* note 200, at 11.

<sup>215</sup>*Id.* at 11-12.

<sup>216</sup>*Id.* at 12.

<sup>217</sup>Families USA Foundation, *supra* note 205, at 10.

<sup>218</sup>*Id.*

<sup>219</sup>*Id.*

that the high cost of R&D is responsible for the high price of pharmaceuticals in the U.S. While the cost of R&D spending is still extremely large, these tax credits should be taken into account. These tax breaks make R&D expenditures very attractive, and the pharmaceutical industry would be less likely to cut back in this area if profits were reduced.

## **2. Profitability of Pharmaceutical Companies**

The profitability of the pharmaceutical industry is one factor that may account for the high prices of prescription drugs in the U.S. According to a 2001 survey, the pharmaceutical industry was the most profitable industry in the U.S. for each of the preceding ten years.<sup>220</sup> On average, the industry's profits were one and one-half times that of the next most profitable industry.<sup>221</sup> These profits also translate into shareholder value. From 1996 to 2001, shareholders received an annual rate of return of 18.4%, which was twice the 9.2% average return to shareholders of Fortune 500 companies.<sup>222</sup>

The executives in the pharmaceutical industry are handsomely compensated. In 2001, the average annual income of the highest-paid executive in the industry (averaged from nine pharmaceutical manufacturers) was nearly \$21 million.<sup>223</sup> That figure does not include unexercised stock options, which was \$48 million on average in 2001.<sup>224</sup> The highest paid executive in the industry was Bristol-Myers Squibb's former Chairman

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<sup>220</sup>*Id.* at 13.

<sup>221</sup>*Id.*

<sup>222</sup>*Id.*

<sup>223</sup>*Id.* at 5.

<sup>224</sup>*Id.* at 6.

and CEO, whose compensation package, exclusive of unexercised stock options, was nearly \$75 million.<sup>225</sup>

The implications of these figures on the industry's profits are that the drug companies could lower their prices significantly yet still be profitable. However, not every drug company is profitable. For example, in 2001, Genzyme recorded a 9% loss, and Pharmacia and Abbot Labs both reached only 7% profit.<sup>226</sup> There is nothing wrong with high profits in themselves, and pharmaceutical companies are not the only companies posting profits. For example, Coca-cola made a 20% profit in 2001, while Microsoft made a 20% profit and Mellon Financial made 33% profit.<sup>227</sup> This comparison merely shows that companies exist to make profit, and should not necessarily be demonized for it. Executive compensation in the pharmaceutical industry looks paltry in comparison with other executive compensation packages. In 2001, the CEO of Oracle made more than \$700 million in salary, including stock options.<sup>228</sup> The CEO of Cisco Systems made \$226.7 million, and the CEO of Phillip Morris made \$131.7 million.<sup>229</sup>

A comparison of executive compensation arguably misses the point. It is to be expected that most “innovator” drug companies make above-average profits,<sup>230</sup> The more risk there is in a venture, the higher the potential profits. As explained above, the process of creating and developing new drugs is a very risky business. The high profits associated with the high risk are what induce investors to invest in the company. This capital is what enables the industry to produce new and innovative drugs.

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<sup>225</sup> *Id.*

<sup>226</sup> Dr. Merrill Matthews Jr, *Prescription Drug Prices and Profits*, Institute for Policy Innovation (Jan. 9, 2003), *available at* <http://www.ipi.org>.

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

<sup>229</sup> *Id.*

<sup>230</sup> *Id.*



High profits for the pharmaceutical industry result in innovation and enable Americans to have access to the most innovative drugs in the world. Americans have immediate access to new drugs in part because of the lack of government price regulation, whereas foreign consumers often experience delays due to regulations that require price negotiations and drug reimbursements before a new drug is available to the public.<sup>231</sup> Virtually all drug innovation is now concentrated in the U.S. because of foreign price controls. The American public receives these innovative new drugs quickly, in part because of the profitability of the pharmaceutical industry.

The amount of innovation in new drugs brought to the market is a controversial issue. From 1989 to 2000, 65% of the new drugs approved by the FDA were for drugs that contained active ingredients available in products that were already on the market.<sup>232</sup> Those approvals were mostly for incremental changes to existing drugs, such as changes in dosing or method of administration.<sup>233</sup> Only 24% of FDA approvals from 1989 to 2000 were eligible for FDA's priority review, a review process for drugs that offer a significant clinical advance over products already on the market.<sup>234</sup> It could be argued that Americans are actually not receiving innovative new drugs, but rather updates of existing drugs that provide only marginal improvements.

For example, Claritin, Schering-Plough's "blockbuster" antihistamine, was losing its patent protection. Schering then introduced Clarinex, a "next-generation" non-sedative antihistamine, to replace Claritin.<sup>235</sup> Clarinex is approved for outdoor and indoor allergies, whereas Claritin is approved only for outdoor allergies.<sup>236</sup> Claritin and Clarinex are important drugs for Schering-Plough – in 2001 it reported combined Claritin/Clarinex sales of \$3.2 billion.<sup>237</sup> In part, the industry is focusing on developing reformulations of

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<sup>231</sup>Creech, *supra* note 80, at 603.

<sup>232</sup>Families USA Foundation, *supra* note 205, at 11 (citing Michie Hunt, *Changing Patterns of Pharmaceutical Innovation*, Washington: National Institute for Health Care Management Research and Education Foundation, (May 2002)).

<sup>233</sup>*Id.*

<sup>234</sup>*Id.* (citing Michie Hunt, *supra* note 232).

<sup>235</sup>*Id.*

<sup>236</sup>*Id.*

<sup>237</sup>*Id.*

existing products because it is not discovering new drugs as quickly as it did in the 1990s.<sup>238</sup> With fewer discoveries being made and the resulting marginal improvements to existing drugs, the argument about innovation seems to become more of a laudable goal than a convincing defense of high profits. Nevertheless, there certainly has been innovation and breakthroughs in the pharmaceutical industry. There are currently over 400 new medicines in development in the fight against cancer, 123 new medicines in development for heart disease and stroke, and 83 drugs and vaccines in development for HIV/AIDS.<sup>239</sup> The development of these new and innovative medicines that have life-saving potential might not have been possible if it were not for the high profits of the industry that encouraged investment in the first place.

### **3. Marketing, Advertising, and Administration Expenses**

Another explanation for the high prices of drugs in the United States is the high cost of marketing, advertising, and administration. Over the past decade, pharmaceutical companies have steadily increased their marketing, advertising, and public relations budgets. In 1997, the FDA removed restrictions on direct to consumer advertising, thereby increasing advertising expenditures by almost 50% from 1996 to 1997.<sup>240</sup> Advertising expenditures exceeded \$1 billion per year in 1997, and reached an estimated \$1.4 billion per year in 1998.<sup>241</sup> In 2001, the pharmaceutical industry spent \$19.1 billion on promotion.<sup>242</sup>

The pharmaceutical industry devotes more resources to marketing, advertising, and administration than it does on R&D. Most drug companies spend an average of 11-15% of profits on R&D, while spending 25-40% of profits on marketing and advertising.<sup>243</sup> For example, in 2002 Pfizer spent nearly \$5.2 billion on R&D,

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<sup>238</sup> *Id.*

<sup>239</sup> Pharmaceutical Research and Manufacturers' Association, *supra* note 200, at 16.

<sup>240</sup> Tamar V. Terzian, *Notes and Comments: Direct-to-Consumer Prescription Drug Advertising*, 25 Am. J. L. & Med. 149, 151 (1999).

<sup>241</sup> *Id.*

<sup>242</sup> Kaiser Family Foundation, *supra* note 193.

<sup>243</sup> Michele Creech, *supra* note 80, at 607.

yet spent \$10.8 billion on selling, informational and administrative expenses.<sup>244</sup> The disparity in expended resources extends to human capital as well. Brand-name drug manufacturers employ 81% more people in marketing departments than in research.<sup>245</sup> Between 1995 and 2000, research staffs decreased by 2%, while marketing staffs increased by 59%. Industry analysts claim the increase in spending on marketing and advertising has resulted in a 19% increase in consumer prescription drug spending in 2000.<sup>246</sup>

Critics of the pharmaceutical industry suggest that this increase in consumer prescription drug spending does not promote the health of the consumer. Instead, physicians are pressured by their patients to prescribe drugs that the patient has seen advertised.<sup>247</sup> Many physicians relent to patient pressure, even if it is not in the best interest of the patient.<sup>248</sup> Physicians believe that superficial and misleading advertisements create unreasonable or inappropriate patient expectations for product effectiveness and often lead patients to request inappropriate products for their medical needs.<sup>249</sup>

The pharmaceutical industry points out that as a whole, the industry spends more on R&D than on promotion. In 2001, the industry spent \$30.3 billion on R&D and \$19.1 billion on all promotional activities.<sup>250</sup> More than half of the industry's total marketing expenses went to providing free samples to doctors for distribution to patients.<sup>251</sup> The industry defends its choice to engage in advertising. PhRMA cites a 2002

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<sup>244</sup>Pfizer, *2002 Annual Report*, at 44, available at [http://www.pfizer.com/are/investors\\_reports/annual\\_2002/pfizer2002.pdf](http://www.pfizer.com/are/investors_reports/annual_2002/pfizer2002.pdf)

<sup>245</sup>Families USA Foundation, *supra* note 205, at 13 (citing Alan Sanger and Deborah Socolar, *Drug Industry Marketing Staff Soars While Research Staffing Stagnates*, Boston University School of Public Health, Health Reform Program (Dec. 6, 2001)).

<sup>246</sup>Creech, *supra* note 80, at 607-8.

<sup>247</sup>Terzian, *supra* note 240, at 158.

<sup>248</sup>*Id.*

<sup>249</sup>*Id.*

<sup>250</sup>Pharmaceutical Research and Manufacturers' Association, *supra* note 200, at 14. There is an apparent discrepancy between the claim that companies spend more on marketing on R&D, yet the industry as a whole spends more on R&D than promotion. However, I speculate that this could be explained by the fact that many smaller drug companies do not do advertising. They engage in research and develop drugs that they license to larger companies, or they are acquired by larger companies. The largest companies that do engage in advertising spend more on advertising than R&D.

<sup>251</sup>*Id.*

Prevention Magazine survey that found that since 1997, 61 million Americans have spoken with their doctor about a condition for the first time after watching an advertisement.<sup>252</sup> Patients who are already taking prescription medicines respond well to advertisements, with 17% reporting that seeing an ad made them more likely to take their medication regularly, and 12% reporting that seeing an ad made them more likely to refill a prescription.<sup>253</sup> The industry attributes an increase in sales growth in recent years to direct to consumer advertising and other promotional efforts.<sup>254</sup>

#### **4. Patent Protection**

The patent system also accounts for the prices of prescription drugs. Patents are granted to originator products to allow an opportunity for developers to recoup R&D expenses, as well as to reward innovation. Patents bar competition for generic imitators for the term of the patent which, after factoring in clinical trials and FDA approval, is ten to twelve years.<sup>255</sup> The pharmaceutical industry asserts that patents provide a necessary incentive for the increasing expenditures on R&D, and maintains that weaker patent protection would reduce innovation.<sup>256</sup>

When the patent term is over, generic drugs will enter the market and prices will fall. However, generic entry into the market may be delayed for a number of reasons, including infringement suits filed against generic competitors, patent holders reformulating their drugs just prior to expiration with the intent to switch prescriptions to the newly reformulated drug (recall the Claritin/Clarinet discussion), and patent

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<sup>252</sup>*Id.*

<sup>253</sup>*Id.*

<sup>254</sup>Creech, *supra* note 80, at 608.

<sup>255</sup>*Id.* at 604.

<sup>256</sup>Pharmaceutical Research and Manufacturers' Association, *supra* note 200, at 66.

holders who produce their own line of generics to weed out competition.<sup>257</sup> Therefore, these delays can in effect extend the patent term and prevent price competition for a number of years.

Besides barring generic competition, the patent system may contribute in another way to the high price of pharmaceuticals. Because of the ten to twelve year life span of a patent, the pharmaceutical companies must recoup their investment in a relatively short period. If the patent term were longer, generic drugs would be slower to enter the market, but it is possible that prescription drugs would cost less because of the longer period over which the pharmaceutical companies could recoup their investment.

## **5. Increase in the Prescribing of Drugs**

An increase in the demand of pharmaceuticals has also led to higher prices.<sup>258</sup> Prescription drug spending in the U.S. increased by 19% in 2000,<sup>259</sup> and increased by an additional 16% in 2001.<sup>260</sup> The increase in spending is driven by the increase in the prescribing and utilization of drugs. Some of this increase is attributed to the substitution of drugs in place of medical procedures as alternative means of treatment.<sup>261</sup> Some of this increase is attributed to the fact that Americans are getting older. Another reason for the increase is that direct to consumer advertising has placed pressure on physicians to prescribe medications that consumers request, but that may not be necessary. The end result is that the increased demand of drugs has lead to higher prices.

## **Factors that Affect Prescription Drug Prices in Canada**

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<sup>257</sup>Creech, *supra* note 80, at 605.

<sup>258</sup>*Id.* at 606.

<sup>259</sup>*Id.* at 605.

<sup>260</sup>Kaiser Family Foundation, *supra* note 193.

<sup>261</sup>Creech, *supra* note 80, at 606.

There is general agreement that many prescription drugs cost less in Canada. However, there is less agreement about the size of the difference. The lack of consensus is largely because of key differences among studies in the nature of the comparison of drug prices between countries.<sup>262</sup> For example, certain price comparisons measure a drug's price at different points in the distribution chain - some focus on retail prices while others look at prices charged by manufacturers.<sup>263</sup> Studies also differ with regard to which payer's price is being measured. In the United States, different customers pay different prices. For example, customers who pay cash (the uninsured) typically pay the highest prices, while insurers and managed care plans are able to negotiate discounts and manufacturer rebates.<sup>264</sup> Government programs are able to get even deeper price reductions.<sup>265</sup> By contrast, in Canada, there is little variation in prices paid by different customers.<sup>266</sup> Many studies do not take account of these price differentials within the U.S.

Studies differ in the sample of drugs being compared. This sampling difference often reflects the different goals of the studies. For example, one study may focus only on price differences among patented drugs, another may be interested only in price differences among drugs with high sale volumes, while another might seek to provide a broad comparison of all commonly used drugs.<sup>267</sup> The different sampling of drugs often produces discrepancies in the price differentials produced.

Another factor contributing to the lack of consensus about drug price differences between the U.S. and Canada is difficulty over exchange rate issues. Researchers must choose an exchange rate that is not sensitive to day-to-day currency fluctuations but nevertheless captures the costs to citizens in one country of buying

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<sup>262</sup>AARP Public Policy Institute, *Prescription Drug Prices in Canada, Issue Brief IB62*, at 5, available at [http://research.aarp.org/health/ib62.can\\_rx.pdf](http://research.aarp.org/health/ib62.can_rx.pdf).

<sup>263</sup>*Id.*

<sup>264</sup>*Id.*

<sup>265</sup>*Id.*

<sup>266</sup>*Id.*

<sup>267</sup>*Id.*

drugs in another country.<sup>268</sup> Another technical issue is choosing the appropriate weight to give to each drug's price difference in the process of calculating an aggregate price differential.<sup>269</sup>

Research by Patricia Danzon illustrates the difficulties of cross-country studies. Her results show that measures of international price differences for pharmaceuticals are very sensitive to the unit for measuring price, sample, and weights used.<sup>270</sup> For example, price-per-gram comparisons, based on a weighted market basket of drugs created using U.S. market share figures, showed that Canadian prices-per-dose were 3% higher than U.S. prices, and prices-per-gram were 13% lower.<sup>271</sup> Using Canadian market share weights, Canadian prices-per-dose were 45% lower than U.S. prices.<sup>272</sup> This means that both Canadians and Americans tend to pay comparatively less for the drugs they use comparatively more often.<sup>273</sup> Danzon's work illustrates the difficulties of doing cross-country studies properly, and the ease with which they can be manipulated. Her work illustrates that we should give pause when we hear alarmist claims about how much more Americans pay for drugs.<sup>274</sup>

Nevertheless, it seems clear that there is some sort of price differential between the U.S. and Canada, regardless of how big this differential is. The following chart gives an example of these price differentials.<sup>275</sup>

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<sup>268</sup> *Id.*

<sup>269</sup> *Id.*

<sup>270</sup> Stephen R. Latham, *Pharmaceutical Costs: An Overview and Analysis of Legal and Policy Responses by the States*, 24 J. LEGAL MED. 141, 146 (2003) (citing Patricia Danzon, *Price Comparisons for Pharmaceuticals: A Review of U.S. and Cross-National Studies* (Apr. 1999)).

<sup>271</sup> *Id.*

<sup>272</sup> *Id.*

<sup>273</sup> *Id.*

<sup>274</sup> *Id.*

<sup>275</sup> *Drug Importation Policy: Current Laws and Issues for Debate*, *supra* note 12, at 263 (as cited by Representative Gil Gutknecht (MN-R)). The price comparison is not as convincing, given Danzon's critique. Nevertheless, the comparison serves as an example of possible price disparities between the two countries.

	<u>DRUG</u>	<u>U.S. PRICE</u>	<u>CANADIAN PRICE</u>
Augmentin	\$55.50	\$12.00	
Cipro	\$87.99	\$53.55	
Claritin	\$89.00	\$37.50	
Coumadin	\$64.88	\$24.94	
Glucophage	\$124.65	\$26.47	
Norvasc	\$67.00	\$46.27	
Paxil	\$83.29	\$44.35	
Pravachol	\$85.60	\$40.00	
Premarin	\$55.42	\$22.46	
Prempro	\$31.09	\$14.33	
Prilosec	\$112.00	\$59.00	
Prozac	\$91.08	\$20.91	
Synthroid	\$33.93	\$13.22	
Zestril	\$40.49	\$20.44	
Zocor	\$123.43	\$45.49	
Zoloft	\$114.56	\$47.40	

The question arises as to how to account for this price differential? One reason is that Canada's federal Patented Medicine Prices Review Board (PMPRB) regulates the maximum prices that can be charged for patented drugs. The PMPRB is a quasi-judicial body that regulates the price that a manufacturer can charge by determining maximum levels for introductory prices of new patented drugs and increases in the prices of extant drugs.<sup>276</sup> The PMPRB's jurisdiction includes patented drugs sold by manufacturers to Canadian hospitals, wholesalers, retail pharmacies, and others. The PMPRB was established because of a change in the law which gave Canadian patent holders an exclusive right to market the drug for the first seven to ten years of the patent term. Prior to this, patented pharmaceutical products in Canada had no right of market exclusivity. To address concerns that market exclusivity would lead to substantial increases in the prices for patented drugs, the law also established the PMPRB and gave it authority to take certain measures to keep

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<sup>276</sup>AARP Public Policy Institute, *supra* note 262, at 12.



patent drug prices from becoming “excessive.”<sup>277</sup>

In setting prices, the PMPRB considers the drug’s Canadian price, the price in other markets, the price of similar medicines within Canada, Canada’s Consumer Price Index, and the cost of making and marketing the drug.<sup>278</sup> If the PMPRB determines that the price of a drug is too high, it has significant power to take action against companies that do not comply with its guidelines. It can induce the manufacturer to voluntarily reduce the price, it can hold a public hearing and can either order the maker to reduce the price or take it away its market exclusivity, or it can require the patent owner to reduce the price of another drug or remit money to the government.<sup>279</sup> It appears that the PMPRB has been effective at restraining prices of patented drugs. Average annual price increases for patented drugs in Canada have fallen substantially during the time that the PMPRB has been operating, and increases have been at or around zero percent since 1992.<sup>280</sup>

Another reason for lower-priced drugs in Canada is that public and private third-party purchasers in Canada, particularly the provincial drug benefit plans, have adopted cost management approaches.<sup>281</sup> The benefit plans apply clinical evaluations to identify therapeutically similar drugs and negotiate with manufacturers in order to get the best price among similar products. Because approximately 90% of Canadian citizens over the age of sixty-five have some form of prescription drug coverage, mostly through provincial government health programs, the government can negotiate bulk purchasing contracts for pharmaceuticals.<sup>282</sup> Both the public and private benefit plans evaluate drugs by using prices and cost-effectiveness data, international price comparisons and reference pricing.<sup>283</sup> They also manage costs by utilizing substantial generic substitution and pharmacy reimbursement policies.<sup>284</sup>

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<sup>277</sup> *Id.*

<sup>278</sup> Khosravi, *supra* note 206, at 433.

<sup>279</sup> *Id.*

<sup>280</sup> AARP Public Policy Institute, *supra* note 262, at 13.

<sup>281</sup> *Id.* at 11.

<sup>282</sup> *Drug Importation Policy: Current Laws and Issues for Debate*, *supra* note 12, at 264.

<sup>283</sup> *Id.*

<sup>284</sup> *Id.*

There are additional possible causes for the lower prices in Canada. One reason could be the higher standard of living in the U.S. In 2001, the U.S. Gross Domestic Product per capita was 55% greater than Canada.<sup>285</sup> Almost all goods and services, not just prescription drugs, cost less in Canada because Canadian incomes are decreasing relative to those of Americans.<sup>286</sup>

Another possible explanation is that the U.S. is a more litigious country than Canada, and the higher prices in part are a reflection of the costs of legal liability. Many federal and state regulatory mandates impose a greater risk of product liability litigation on pharmaceutical manufacturers in the U.S. One study suggested that one-third to one-half of the price differentials between the U.S. and Canada in 1990 were due to the higher costs of protection from legal liability in the U.S.<sup>287</sup> The study also noted that Canadian courts limited compensation for personal injury to C\$250,000 and that Canadian judges rarely awarded large liability settlements.<sup>288</sup>

Yet in the U.S., generic drugs, which comprise roughly half of all prescriptions, are cheaper than both Canadian branded drugs and Canadian generic drugs.<sup>289</sup> Competition in the U.S. market lowers generic drug prices so they are lower than drug prices abroad.<sup>290</sup> For example, of the seven biggest selling chronic-use drugs for which first U.S. generic entry occurred in the last ten years (alprazolam, clonazepam, enalapril, fluoxetine, lisinopril, metformin, and metoprolol), only one (metformin) sold for less in Canada either generically or as a brand name.<sup>291</sup> Furthermore, metformin did not become available generically in the U.S. until January

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<sup>285</sup>Khosravi, *supra* note 206, at 433.

<sup>286</sup>*Id.* at 434.

<sup>287</sup>AARP Public Policy Institute, *supra* note 262, at 16.

<sup>288</sup>*Id.*

<sup>289</sup>Office of Planning, FDA White Paper, *Generic Drug Prices in the U.S. are Lower than Drug Prices in Canada* (Nov. 2003), at <http://www.fda.gov/oc/whitepapers/drugprices.html>.

<sup>290</sup>*Id.*

<sup>291</sup>*Id.*

2002, so U.S. generic prices may not have fallen to the level they will eventually reach.<sup>292</sup> The lower price of generic drugs in the U.S. calls into question the notion that prescription drugs are cheaper in Canada, and suggests that encouraging the use of generic drugs in the U.S. could achieve substantial savings.

### **How Would Reimportation Affect Both U.S. and Canadian Drug Prices?**

Both Secretary Shalala and Secretary Thompson determined that price savings to U.S. consumers under a reimportation system are speculative. In part this is because of the costs associated with implementing a reimportation system, including the costs of product documentation, sampling, testing authentication, repackaging, shipping, and distribution.<sup>293</sup> These requirements would be burdensome and costly for potential importers, and would likely increase prices beyond the sales price manufacturers offer to foreign recipients.<sup>294</sup> Another factor that would directly affect drug prices if reimportation is established is that each intermediary entity in the product distribution chain, from the first foreign recipient through additional foreign distributors to the U.S. importer, will likely incorporate a profit margin into its respective sales price.<sup>295</sup> These successive profit margins have the potential to substantially erode any differences between the price of the drug in Canada and its price after reimportation.<sup>296</sup>

Under a reimportation system, drug manufacturers may establish contractual agreements with differential pricing for Canadian consumption versus reimportation to the U.S.<sup>297</sup> The Canadian government would likely support such differential pricing to protect the price controls they have established for their health care programs.<sup>298</sup> To the extent that such differential pricing occurs, it could reduce any savings to the U.S.

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<sup>292</sup> *Id.*

<sup>293</sup> Tommy Thompson, U.S. Dept. of Health and Human Services Response to Sen. James Jeffords on Drug Reimportation, Attachment B: Assessment of the Potential for Cost Reductions Resulting from the Medicine Equity and Drug Safety Act of 2000, Jul. 9, 2001, *available at* <http://www.fda.gov/oc/po/thompson/medsact.html>.

<sup>294</sup> *Id.*

<sup>295</sup> *Id.*

<sup>296</sup> *Id.*

<sup>297</sup> *Id.*

<sup>298</sup> *Id.*

consumer.

Currently, the Canadian drug market is less than 10% of the U.S. drug market.<sup>299</sup> A reimportation system could greatly increase the Canadian demand for prescription drugs, since many of those drugs would subsequently be imported to the U.S. This larger demand could lead to higher prices in Canada, and the price differential between the U.S. and Canada would therefore be reduced. The Canadian government would have strong incentives to impose restrictions or tariffs to ensure adequate supply of prescription drugs in their own country, as well as to prevent an increase in price. In addition, drug manufacturers may continue to curtail the supply of drugs to Canadian wholesalers and pharmacists and withhold the amount they feel is intended to fill prescriptions from American consumers.<sup>300</sup> The supply of drugs in Canada would remain the same but the demand for drugs would increase. This could cause a shortage of drugs in Canada. Because of the price controls, prices may not increase. However, a black market of prescription drugs could develop causing an increase in price, as well as concerns about counterfeiting.

Prescription drug prices in the U.S. could increase as a result of a reimportation system. If drug manufacturers sold significantly more drugs to Canada, prices in the U.S. might rise so that the drug manufacturers could recoup their R&D costs in the drugs that are sold in the U.S. to offset the loss from increased sales to Canada. However, because of the costs involved with reimportation discussed above, drugs that are imported from Canada would also cost more than they cost in Canada. Therefore, not only is it possible that a reimportation system would not produce cost savings for U.S. consumers, but it also may actually increase the prices of prescription drugs for U.S. consumers, contrary to the intent of the system.

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<sup>299</sup>Tyler Pearson, *Drug-import Issue a Hot Button: Pricing Puts Statehouses, Washington in Middle*, Medill News Service, CBS MarketWatch (Apr. 24, 2004), at

<http://cbs.marketwatch.com/news/story.asp?guid={02BB1E24-AA08-442B-A53D-C2577E33C0D6}&siteid=mktw&dist=&archive=true>.

<sup>300</sup>See Bloomberg News, *supra* note 100.

## Prescription Drug Prices Have a Disproportionate Effect on Senior Citizens

Reimportation is an important issue because Americans are spending a great deal on prescription drugs. Spending for prescription drug costs is the fastest-growing segment of the U.S. health care costs.<sup>301</sup> In 1991, U.S. spending on prescription drugs was \$140.6 billion.<sup>302</sup> Medicare beneficiaries (people who are sixty-five or older or disabled) account for about 40% of that spending although they make up less than 15% of the U.S. population. The Medicare program provides broad insurance coverage for many health needs, but it provides only limited coverage of drugs not dispensed during a hospital stay. The Congressional Budget Office expects Medicare beneficiaries' drugs costs to rise rapidly over the next decade.<sup>303</sup> In 2002, Medicare beneficiaries spent almost \$87 billion in outpatient prescription drugs.<sup>304</sup> That figure is projected to rise to more than \$128 billion by 2005.<sup>305</sup>

The average spent on prescription drugs by those sixty-five and older was \$884 in 2001.<sup>306</sup> The spending on prescription drugs is concentrated among people with chronic conditions requiring long-term drug therapy. Although only 17% of Medicare beneficiaries will spend more than \$5,000 on prescription drugs in 2005, their combined spending will make up nearly 54% of total drug expenditures by Medicare beneficiaries that year.<sup>307</sup>

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<sup>301</sup> *Prescription Drugs and Medicare: Rising Costs and Declining Spending*, 82 CONG. DIGEST 270 (Nov. 2003) (from *Issues in Designing a Prescription Drug Benefit for Medicare*, Congressional Budget Office (Oct. 2002)).

<sup>302</sup> Kaiser Family Foundation, *supra* note 193.

<sup>303</sup> *Prescription Drugs and Medicare: Rising Costs and Declining Spending*, *supra* note 301.

<sup>304</sup> *Id.*

<sup>305</sup> *Id.*

<sup>306</sup> Kaiser Family Foundation, *supra* note 193.

<sup>307</sup> *Prescription Drugs and Medicare: Rising Costs and Declining Spending*, *supra* note 301.

In the fall of 1999, 38% of Medicare beneficiaries had no prescription drug coverage.<sup>308</sup> Throughout the year of 1999, 25% of beneficiaries had no coverage.<sup>309</sup> They must pay for all their drug costs out of pocket. The other three-quarters of Medicare beneficiaries obtain drug coverage through employer-sponsored sources, Medicare HMO's, private HMO's, Medicaid, or medigap.<sup>310</sup> These supplemental plans differ greatly in the extent of coverage they provide.<sup>311</sup> The availability and comprehensiveness of supplemental drug coverage may be declining.<sup>312</sup>

Medicare beneficiaries who lack drug coverage tend to be people in the low to middle part of the income distribution.<sup>313</sup> This is because people with higher incomes are more likely to have either employment-based plans or individually purchased medigap policies, which charge high premiums on drug coverage.<sup>314</sup> People with the lowest income qualify for drug benefits from Medicaid or from State-sponsored pharmaceutical assistance programs.<sup>315</sup>

Medicare beneficiaries who have drug coverage have more prescriptions filled, on average, than Medicare beneficiaries without drug coverage.<sup>316</sup> This disparity either means that Medicare beneficiaries with prescription drug coverage are unnecessarily taking more prescription drugs because they are not paying out of pocket for them, or that people without prescription drug coverage are not taking needed medications because they cannot afford them.

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<sup>308</sup>Kaiser Family Foundation, *supra* note 193.

<sup>309</sup>*Id.*

<sup>310</sup>*Id.*

<sup>311</sup>*Prescription Drugs and Medicare: Rising Costs and Declining Spending*, *supra* note 301.

<sup>312</sup>*Id.*

<sup>313</sup>*Id.*

<sup>314</sup>*Id.*

<sup>315</sup>*Id.*

<sup>316</sup>*Prescription Drugs and Medicare: Rising Costs and Declining Spending*, *supra* note 301, states that Medicare beneficiaries with drug coverage had an average of 32 prescriptions filled in 1999, while beneficiaries without drug coverage had 25 prescriptions filled in 1999. Meanwhile the Kaiser Family Foundation, *supra* note 193, states that in 1999, the average number of prescriptions filled for Medicare beneficiaries with drug coverage was 25, while the average filled for beneficiaries without drug coverage was 17.5.

This discussion of Medicare beneficiaries reflects that prescription drug prices are an important issue for the U.S. population over sixty-five. This is because of the disproportionate use of prescription drugs by the Medicare population, as well as the lack of prescription drug coverage for many Medicare beneficiaries who must pay for prescription drugs out of pocket. The issue of reimportation of prescription drugs is especially important to this population.

A reflection of this is a letter the CEO of the American Association of Retired Persons (AARP) wrote to two Congressmen expressing AARP's support of prescription drug reimportation legislation. The letter stated that AARP believes that carefully crafted reimportation provisions can be a step in making prescription drugs more affordable for older Americans.<sup>317</sup> While AARP believes that the most important step to make drugs affordable for older Americans is the enactment of prescription drug coverage in Medicare, it also believes that reimportation has the potential to place some downward pressure on the costs of prescription drugs.<sup>318</sup>

### **Is Reimportation the Solution?**

Reimportation offers a seemingly easy solution to the millions of American consumers who feel they are paying too much for prescription drugs. The ease of getting seemingly safe drugs from Canada, either through trips across the border or Internet and mail order sites, has made reimportation the focus for many groups. However, as this paper has illustrated, reimportation is not the ultimate solution to reduce prescription drug costs. Reimportation would jeopardize the safety of the drug distribution system within the U.S. It is at best speculative that American consumers would pay what Canadians currently pay for prescription drugs in a system of reimportation. It is clear that prescription drugs costs need to be lowered,

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<sup>317</sup>Bill Novelli, "Letter from AARP CEO Bill Novelli Expressing AARP's Support of RX Re-importation Legislation," available at <http://www.aarp.org/research/press/presscurrentnews/cn-2003/Articles/a2003-08-18-letterceo.html>.

<sup>318</sup>*Id.*

so that drugs are available to all those who need them. Yet a system that jeopardizes the safety of the American public for uncertain monetary savings should not be implemented.

There is no easy solution to lowering the price of prescription drugs in the U.S. American consumers benefit from the innovative new drugs produced by the pharmaceutical companies. We do not want to hamper innovation; therefore we must allow pharmaceutical companies to recoup the cost of bringing new drugs to market. There are other approaches to reduce prescription drug costs, including getting a prescription drug coverage benefit in Medicare. However, this is not a simple solution.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 includes a prescription drug benefit. However, this prescription drug benefit does not go far enough to address the problem of the high price of prescription drugs. In general, individuals covered by Medicare would choose a prescription drug plan and pay a premium of about \$35 a month with a \$250 deductible.<sup>319</sup> Medicare will pay 75% of the costs between \$250 and \$2,250 in drug spending.<sup>320</sup> Medicare beneficiaries will pay 100% of the drug costs above \$2,250 until \$3,600 in out-of-pocket spending.<sup>321</sup> Medicare will pay about 95% of the costs after \$3,600.<sup>322</sup> This plan will go into effect in 2006.<sup>323</sup>

This plan certainly reduces the burden of the high price of prescription drugs for many individuals, and is a step in the right direction. However, many individuals will still have to pay significant out-of-pocket expenses under this plan. For example, a Medicare beneficiary paying the \$35 a month premium and the \$250 deductible still will pay at least \$670 a year for prescription drugs. A beneficiary who spends \$3600 a year on prescription drugs will still pay \$2520 a year. For individuals on a fixed income who need lifesaving

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<sup>319</sup>Center for Medicare and Medicaid Services, *The Facts about Upcoming New Benefits in Medicare: Medicare Modernization Act of 2003*, at <http://www.medicare.gov/publications/pubs/pdf/11054.pdf>.

<sup>320</sup>*Id.*

<sup>321</sup>*Id.*

<sup>322</sup>*Id.*

<sup>323</sup>*Id.*



prescription drugs, this amount is highly problematic. A more effective Medicare prescription drug plan could have lower monthly premiums, no deductible, would cover drug spending between \$2250 and \$3600, or some combination thereof.

Yet a more comprehensive Medicare prescription drug benefit would not be a cure-all. It would not make drugs affordable for all that need it, and it may benefit some who do not need it. As stated earlier, 38% of Medicare beneficiaries do not have prescription drug coverage.<sup>324</sup> This means that 62% of Medicare beneficiaries currently have prescription drug coverage. For this group, the federal spending will merely substitute for private spending, including the private spending of very wealthy Medicare beneficiaries.<sup>325</sup> A prescription drug benefit within Medicare would also do nothing to reach the large number of Americans who do not have prescription drug coverage but who are not old enough to be eligible for Medicare.

A reimportation system is appealing because it applies universally to all Americans. That may be part of the reason for its widespread popular support. Two million Americans currently import drugs from Canada, either through direct trips or through Internet and mail order services.<sup>326</sup> These people are currently at risk because there are no safeguards on their illegally imported drugs. It seems unlikely that this behavior will stop, unless the FDA prosecutes individuals who are importing drugs for their own use. However, I would think that the FDA would be reluctant to do this. There would be public outrage and a questioning of the federal government's criminal prosecution priorities. Since many Americans are currently importing from Canada, reimportation can put safeguards into place and provide a measure of safety that is currently lacking. Yet it would not be possible for these safeguards to provide the amount of safety assured under

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<sup>324</sup>Kaiser Family Foundation, *supra* note 193.

<sup>325</sup>Latham, *supra* note 270.

<sup>326</sup>Ceci Connolly, *Drug-Importation Foes Speak Out; Industry Backers Have Strong Voice At Public Session*, WASH. POST, Apr. 15, 2004, at A03.

the current system. Given the popular support, and the current legislation pending before Congress, it is possible that a reimportation system will be enacted. If reimportation legislation were enacted it would merely be a band-aid to the problem of prescription drugs costs, and a costly one given the risks involved.